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A PILOT STUDY OF THE
ADEQUACY OF POST-HOSPITAL COMMUNITY CARE
FOR THE ELDERLY

FINAL REPORT

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One prominent response of hospitals to the necessity of controlling costs under the Prospective Payment System (PPS) has been to reduce lengths of stay. Since the introduction of PPS, patients are now more ill on average when they are discharged from hospitals, and thus probably require more health and personal care services upon discharge.

Since the introduction of PPS, extensive concern has been expressed-- by both the public and the Secretary of Health and Human Services and other senior officials of the Department--about the adequacy of post-hospital care for elderly patients discharged to the community. Moreover, Congress has mandated that information on the quality of post-hospital care be included in the Department's annual reports to Congress on PPS.

The current evidence on the adequacy of post-hospital community care is largely impressionistic. A systematic assessment is required to develop objective evidence on the extent of the problems associated with post-hospital care and whether they lead to adverse health outcomes for patients.

Unfortunately, the methodology-available up to now has not been adequate to support a systematic assessment of national scope. The primary limitation of the available methodology is that adequacy-of-care assessments have required a review of individual cases by physicians, which is difficult to implement in a national study and which has been found to be unreliable. This report describes a **new** methodology developed to overcome these limitations and to guide a systematic, national assessment of both the adequacy of **community** post-hospital care for elderly Medicare patients and whether inadequate care leads to adverse health outcomes. Central to this methodology is a series of "guidelines" **which** specify the amount of care that is minimally adequate to prevent adverse health outcomes for patients who exhibit a wide variety of conditions that commonly require post-hospital community care.

This methodology has been implemented in a pilot study. Based on an analysis of pilot study data, this report assesses the validity, effective- ness, and feasibility of the new methodology. The conclusion of this assess- ment is that the methodology is generally valid, feasible, and effective, although some refinements are required. With respect to the guidelines, the

conclusion is that (taken as a group) the guidelines provide a reasonable ⟨ definition of minimally adequate post-hospital community care.

The pilot study results must be considered preliminary. The pilot study was limited only to nine hospitals in two states. In addition, the pilot study encountered a substantial amount of missing data, and some of the estimates are sensitive to the assumptions made about missing data.

Figures 1 and 2 depict the pilot study results on access to post-hospital community care and adverse outcomes. Figure 1 indicates that most (72 to 81 percent with a midpoint of 76 percent) of the post-hospital community care needs of Medicare patients under the guidelines were met.[1] The majority (88 percent) of care needs that were not met involved skilled care. Figure 2 depicts the pilot study results on adverse outcomes. There was only a minority of care needs for which we observed one or more adverse outcomes (4 to 10 percent with a midpoint of 7 percent). Most (slightly over 60 percent) of these outcomes involved morbidities rather than an unexpected use of health care services. While not trivial, outcomes that do not involve unexpected service use are generally less serious than those that do involve such use. In developing these preliminary estimates on care needs and adverse outcomes, we varied several factors, including the treatment of missing data, of problematic measures of outcomes, and of care that may be (but is not typically) provided by a physician. The estimates presented here take these factors into account and represent our best estimate.

A. THE METHODOLOGY

As indicated above, the guidelines are central to the newmethodology for measuring the adequacy of post-hospital community care for the elderly. A number of clinicians with extensive experience in post-hospital community care helped develop the guidelines. Draft guidelines developed in conjunction with the staff of the Geriatrics Section of Boston University Medical Center were reviewed by a consensus panel of distinguished clinicians. The guidelines were revised on the basis of the panel's comments and pretested for a sample of patients recently discharged from the hospital. They were again revised

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[1]In the figures, the midpoints of percentage ranges are used.

FIGURE 1
CARE NEEDS UNDER GUIDELINES

1a)
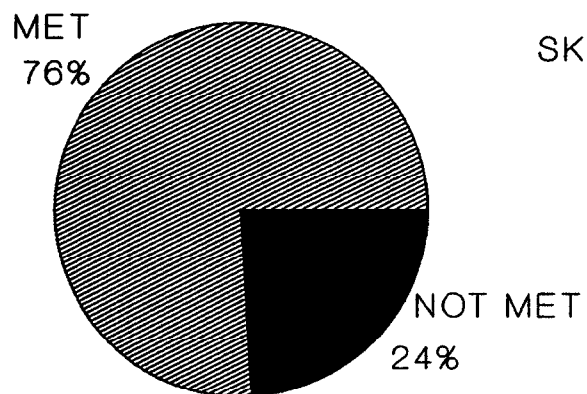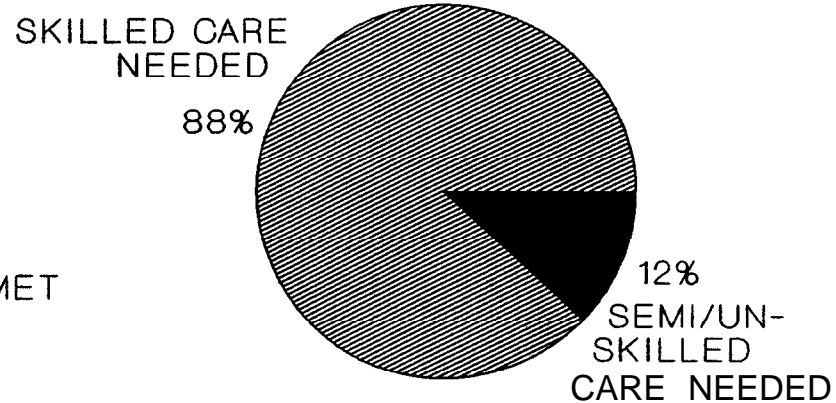
1b)

MET
76%

NOT MET
24%

ALL CARE NEEDS

SKILLED CARE
NEEDED

88%

12%
SEMI/UN-
SKILLED
CARE NEEDED

UNMET CARE NEEDS

NOTE: When the estimates involve a range, the midpoint of
that range is used. The treatment of missing data was
varied in developing the range.

FIGURE 2
ADVERSE OUTCOMES UNDER GUIDELINES
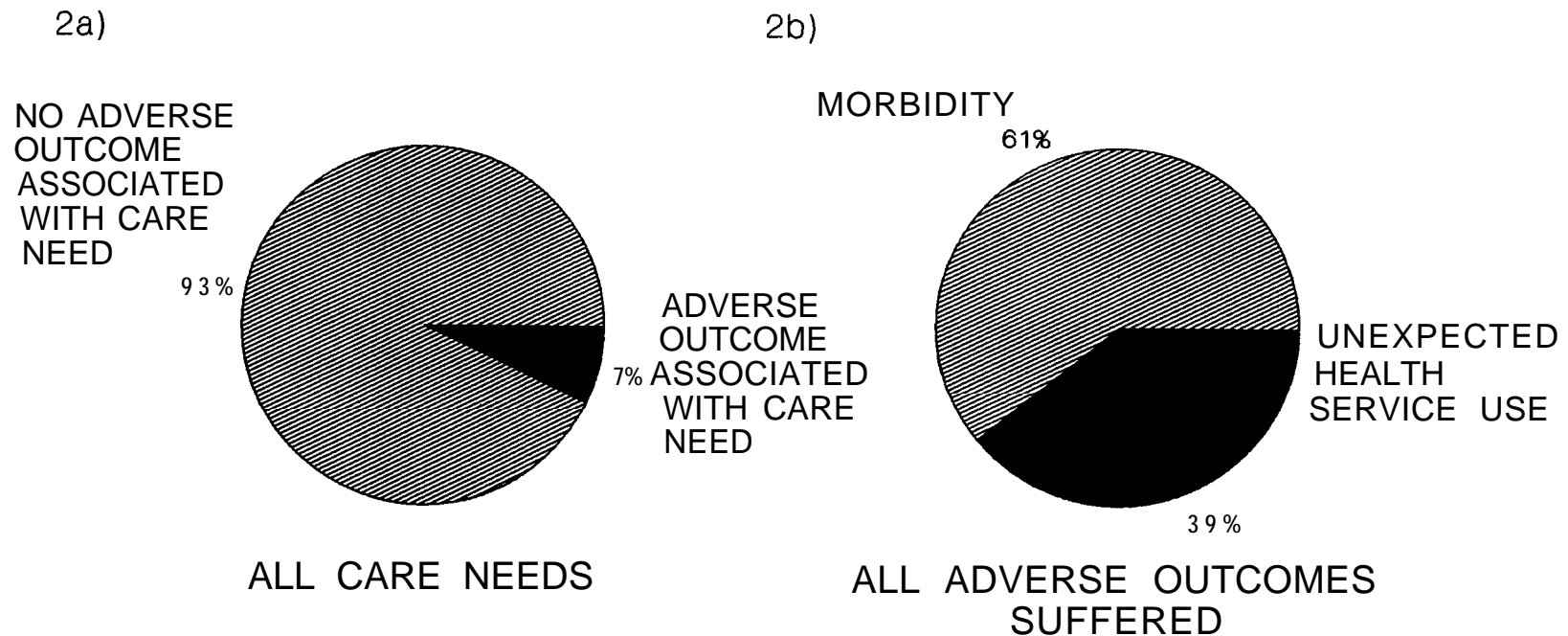
2a)

2b)

NO ADVERSE
OUTCOME
ASSOCIATED
WITH CARE
NEED

93%

ADVERSE
OUTCOME
7% ASSOCIATED
WITH CARE
NEED

MORBIDITY
61%

UNEXPECTED
HEALTH
SERVICE USE

39%

ALL CARE NEEDS

ALL ADVERSE OUTCOMES
SUFFERED

NOTE: When the estimates involve a range, the midpoint of
that range is used. The treatment of missing data
was varied in developing the range; problematic
measures are excluded,

on the basis of the results of the pretest, and were reviewed by the consensus panel prior to their application in the pilot study.

Guidelines were developed **for** 45 distinct conditions (many of which encompass subconditions). Information on medical condition, procedures performed in the hospital, functioning, the availability of informal caregivers (typically family members), and instruction provided in the hospital was used to determine which of the conditions covered by the guidelines were applicable to a given patient. (Multiple guidelines may apply to the same patient.) The guidelines cover both skilled care (primarily nursing and therapy) and semi/unskilled care (primarily personal care) that are needed in the immediate post-discharge period (defined as the two weeks following discharge) by elderly Medicare patients discharged to the community. Care provided in' patients' homes and in physicians' offices and clinics is included. The guidelines for skilled care specify both the minimum number of professional visits necessary in the two weeks after discharge to prevent adverse outcomes and the latest acceptable day (relative to discharge) of the initial professional visit. The guidelines for semi/unskilled care typically specify the frequency with which care must be provided (e.g., the number of times a day) to prevent adverse outcomes. The guideline for each condition includes a list of adverse health outcomes that are clinically associated with inadequate care for that condition. (The guidelines appear as Appendix A to this report.)

In addition to the guidelines, the methodology also includes screening procedures to identify patients with one or more of the **conditions** covered by the guidelines, as well as risk classification procedures to identify patients at high risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes. The screening procedures rely chiefly on information on medical condition, procedures performed in the hospital, and functioning. The risk classification procedures rely on information on the patient's living arrangements, the availability of formal and informal care, the exhaustion of informal caregivers, the receipt of discharge planning, the severity of impairment, the severity of illness, and age. High-risk patients are oversampled relative to their proportion in the population, so as to obtain a sufficient sample of patients who actually experience care that does not meet the guidelines and who suffer adverse outcomes. This sample is used to investigate the relationship between inadequate care and adverse outcomes.

An extensive data collection effort was required to obtain the data necessary for applying the screening and risk classification procedures and the guidelines. The data were derived from two primary sources: (1) hospital medical records and (2) interviews with patients and their caregivers conducted two and six weeks after hospital discharge. Information for screening and risk classification was obtained from the summary sheet of medical records and from screening interviews conducted two weeks after discharge. The detailed information on the patient's condition necessary for determining which guidelines applied to him or her was abstracted from the full hospital medical record. Information on service receipt in the two weeks after discharge was collected in the full interview at two weeks, and information on adverse outcomes was collected in full interviews at two and six weeks. Services received were compared with the guideline specifications to determine whether the patient experienced care that did not meet guidelines.

B.   TESTING AND REFINING THIS METHODOLOGY

The purpose of pilot study was to test the validity of the guidelines, the effectiveness of the screening and risk classification procedures, and the feasibility of the data collection strategy.   The pilot study was also designed to identify any necessary refinements to the methodology to be implemented before a national study is to be undertaken.

1.   The Guidelines

Three analyses were undertaken to test the validity of the guidelines and to identify refinements to them:

   o A statistical analysis of the likelihood of adverse outcomes when
      care met and did not meet the guidelines

   o A comparison of care ordered at the time of hospital discharge
     with care specified under the guidelines

   o A clinical review of 100 pilot study cases

In the remainder of this section, we summarize the results of each of these analyses.

The hypothesis underlying the analysis of **the likelihood of adverse** outcomes is that adverse outcomes will be substantially **more likely when care** does not meet the guidelines than when it does, if the guidelines **(taken as** a group) provide valid specifications of minimally adequate care. This is what we observed. When we corrected a measurement problem involving two outcomes, we estimated large differences in the likelihood of adverse outcomes when care meets and does not meet the guidelines. We estimated that adverse outcomes are 4.5 times as likely when care does not meet the semi/unskilled guidelines and 2.4 times as likely when care does not meet the skilled care guidelines (relative to the likelihood when care meets the guidelines). For all the guidelines combined, we estimated that adverse outcomes are 3.4 times as likely when care meets the guidelines than when it does not. Figure 3 depicts these results. The estimated differences in the likelihood of adverse outcomes are statistically significant for all guidelines and the skilled care guidelines, and approach significance for the semi/unskilled guidelines. Further, when we relaxed or tightened the specifications of the guidelines, we obtained less reasonable results: we estimated that the effect of inadequate care was to <u>reduce</u> adverse outcomes. This finding is encouraging, in that it appears to suggest that the guideline standards are neither too relaxed nor too tight. However, these results also indicate that changes in the specifications for one guideline (the guideline on medication supervision) can have a dramatic effect on estimates of the likelihood of adverse outcomes.

Two hypotheses underlie the comparison of care ordered at the time of hospital discharge (and noted in hospital records) with the care specified under the guidelines. First, if the guidelines cover all types of care commonly provided to elderly patients in the community, we will observe relatively few patients with orders for care to whom no guidelines are applicable. Second, if the guidelines specify minimally adequate care, the amount of care ordered will not be smaller than the amount specified under the guidelines. Both hypotheses were confirmed. At least one skilled guideline was applicable to 89 percent of the patients with orders for nursing or therapy and to 80 percent of the patients with orders for follow-up physician care in the two weeks following discharge. The amount of care specified under the guidelines never exceeded the amount ordered. A review of the cases in which care was ordered but no guideline was applicable indicates that several existing guidelines should be refined, but **major** revisions are unnecessary.

FIGURE 3
LIKELIHOOD OF ADVERSE OUTCOMES
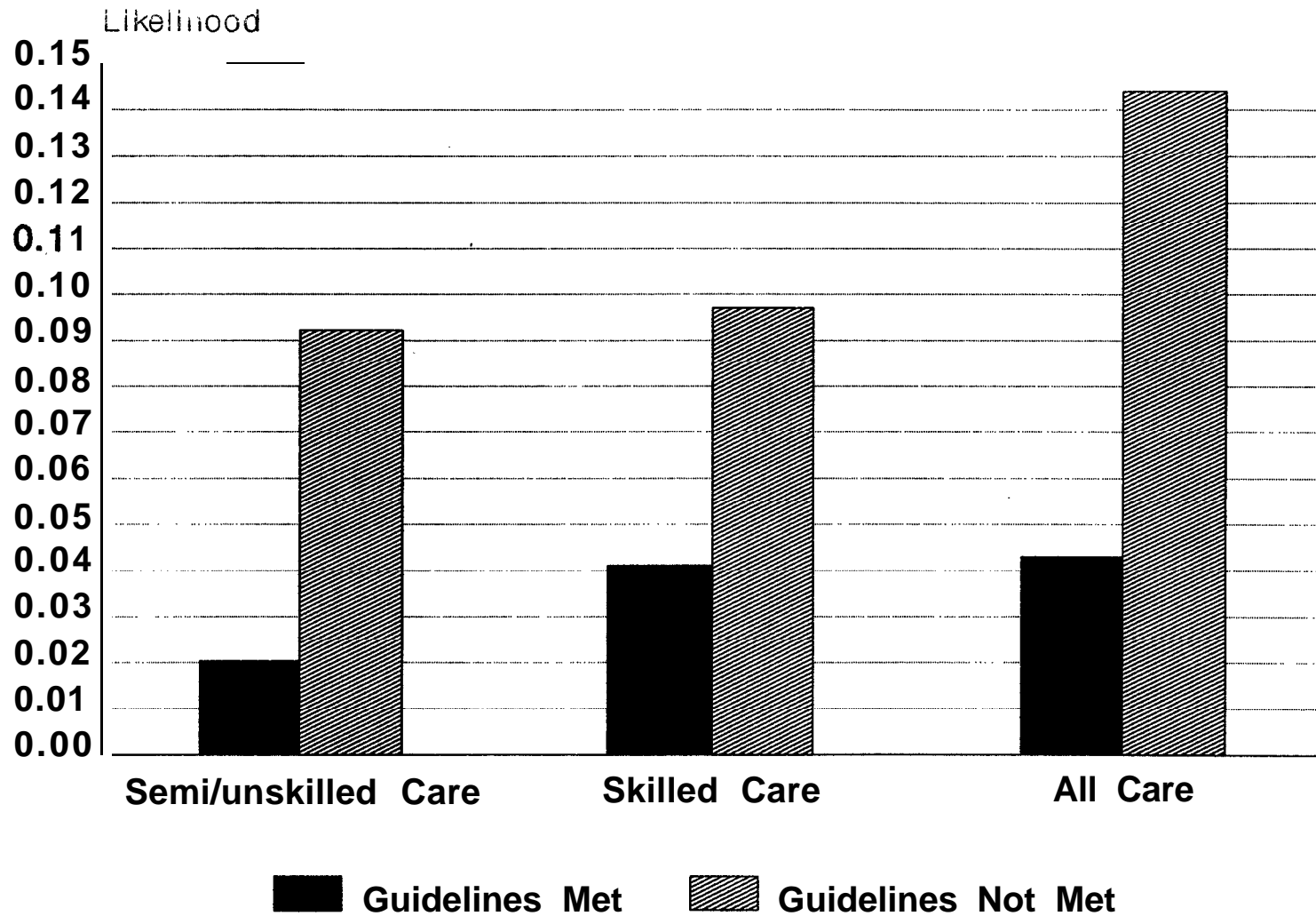
NOTE: Likelihood was estimated using a probit model.
Adverse outcomes have been deleted when
the measures appear to be problematic.

Because the primary purpose of the clinical review was to identify guidelines that needed refining, the sample of cases chosen for review was selected deliberately to include cases in which the guidelines were most likely to be problematic (e.g. , cases in which the patient experienced care that met the guidelines but suffered an adverse outcome). Despite the nature of the sample, the clinicians who conducted the review concluded that, in general, the guideline standards were clinically sound. However, they did suggest refinements to the guidelines and to the procedures for applying them. (The results of the clinical review are presented in a separate report; see Markson et al., 1989.)

While the analysis of the guidelines supports their validity, it also suggests a number of refinements to them. Many of the suggested refinements are relatively trivial (e.g., the inclusion of additional adverse outcomes); others call for subdividing the existing guidelines so that different care may be specified for the subdivisions. For example, one suggested refinement entails subdividing the guideline on diabetic care for patients with and without informal caregivers, with more care specified for the patients without informal caregivers. We recommend that the refinements be reviewed by a clinical consensus panel.

2.   The Effectiveness of Screening and Risk Classification Procedures

The analysis of the effectiveness of the screening procedures compared the need for care according to these procedures with the need for care according the guidelines to determine the extent to which patients to whom at least one guideline applied were incorrectly screened out and, conversely, the extent to which patients to whom no guidelines applied were incorrectly screened in. The guidelines cover a broad scope of care, and at least one guideline was applicable to the vast majority (94 percent) of elderly Medicare patients discharged from the hospital to the community. The screening procedures correctly identified almost all of the patients (97 percent) to whom at least one guideline was applicable. However, the screening procedures were not effective at identifying patients who did not need care under the guidelines. At least one guideline was applicable to about 60 percent of a small sample of cases that had been screened out as not needing care under the guidelines. While these cases represent only a small portion (about 6 percent) of the patients who needed care, refinements to the screening

procedures would be desirable. A review of the cases that were incorrectly screened out suggests that the effectiveness of the screening procedures could be improved substantially by adding items on laboratory testing, follow-up physician care, and specific personal care activities. With these additional items, we estimate that the guidelines would be applicable to fewer than a quarter of the patients screened out as not needing care, and that the patients who were incorrectly screened out would comprise no more than 2 percent of the Medicare patients who need post-hospital community care.

The analysis of the risk classification procedures compared the incidence of care that did not meet the guidelines and of adverse outcomes for patients at high risk and patients **not** at high risk to determine whether patients at high risk exhibited a higher incidence of care that did not meet the guidelines and of adverse outcomes relative to those not at high risk. We observed such a difference. About 29 percent of the patients in the high-risk group experienced care that did not meet the guidelines and suffered adverse outcomes, compared with about 12 percent of the patients not in the high-risk group. When we considered care and outcomes separately, we found a large and statistically significant difference in the incidence of adverse outcomes but not in the incidence of care that did not meet the guidelines. However, the observed difference in the incidence of care that did not meet the guidelines for patients at high risk and not at high risk was attenuated in the pilot study sample due to an artifact of the sample associated with a revision to the risk classification procedures that was implemented after data collection had begun. The evidence suggests that we would have found a larger (and statistically significant) difference in the incidence of inadequate care in the two risk groups had the revised risk classification procedures been in place at the beginning of data collection.

3.   The Feasibility of the Data Collection **Strategy**

The experience of the pilot study indicates that the data collection strategy is generally feasible and deals successfully with a number of operational issues. The cooperation of hospitals was satisfactory: over 80 percent of the hospitals **that were** approached agreed to participate. However, for-profit hospitals were the most reluctant to participate, suggesting that non-participating hospitals may differ systematically from participating hospitals, and that it may be desirable to adjust the results of a national

study for the nonresponse of hospitals. Patients and their caregivers were very cooperative; the completion rates for the interviews ranged from 88 to 99 percent. Selecting the sample of discharged patients, obtaining the information on condition and procedure codes for screening purposes, and processing this information in a timely way did not present intractable problems. However, by using hospital discharge disposition codes to identify patients discharged to the community, we failed to include a small minority of eligible patients who were coded as discharged to an institution, but who were actually discharged to the community.

The major problem with the data collection strategy is the extent of missing data. Missing data precluded determining whether or not a patient had a given condition in about 14 percent of all the potential observations on condition, and missing data precluded determining whether care met the guidelines or adverse outcomes were suffered in about 23 percent of the cases in which the condition could be determined. The actual number of observations lost to analysis due to missing data on condition, care, or outcomes is unknown, but lies between 23 percent and 37 percent. The major cause of the missing data was inconsistency between the hospital medical records and the interview reports. Because medical records were not available for abstraction until quite some time after a patient was discharged and because abstraction is a very time-consuming process, the patient's report of his or her condition was used to determine which interview questions on care and outcomes were asked. If the information in the hospital medical record indicated that the patient had a given condition, but the patient did not report having that condition when interviewed, the guideline for that condition could have been applicable based on the medical records information, but data on care and adverse outcomes would not have been available from the interview. Another major cause of missing data was a failure to find information in the medical record, either because it did not exist or because it was overlooked.

While one cannot hope to eliminate missing data entirely, it is very important that the data collection strategy be revised in a national study to reduce the amount of missing data. We recommend revisions to the data collection strategy to reduce missing data that involve changing the interviews to ask as many questions as possible regardless of the condition reported by the patient, and expanding the "callback" procedures so that

patients are recontacted to resolve inconsistencies between the hospital records data and the interview data and to provide missing data.

Another serious problem with the data collection strategy in the pilot study involves the procedures for abstracting medical records and for the automated application of the guidelines. The clinical reviewers felt that the guidelines had been applied incorrectly in a substantial number of the 100 cases that they reviewed. Further investigation indicates that the major factors accounting for the differences in application of the guidelines were the use of different decision rules under the automated procedures and in the clinical review, and difficult-to-locate information that was overlooked during abstraction for automated application of the guidelines but not during the clinical review. Most of the cases in which decision rules differed involved cases in which information on functioning in the medical record and the interview was inconsistent. To eliminate these inconsistencies, we recommend that the interview be used as the primary data source on functioning. (Presently, the medical record is the primary source.) We also recommend refining the medical records abstraction and the automated procedures for applying the guidelines to deal with ambiguous cases. Finally, we recommend increasing the time devoted to medical records abstraction.

I. INTRODUCTION

This introductory chapter briefly reviews the policy issues to be addressed in a study of the adequacy of post-hospital care in the community and the purpose and scope of the pilot study. It provides an overview of the methodology developed in the pilot study to assess the adequacy of post-hospital community care and an overview of the analyses conducted to test and refine that methodology. Finally, this chapter provides an outline of the remainder of the report.

A. POLICY ISSUES TO BE ADDRESSED

Since October 1983, hospitals have been paid for Medicare admissions under a Prospective Payment System (PPS) whereby the reimbursement per case is set in advance. These PPS reimbursement amounts (actually weights) are based on the average resource use by patients who are classified into one of over 450 diagnosis-related groups (DRGs). PPS applies to the overwhelming majority of Medicare hospital patients.. However, certain types of hospitals and special units within covered hospitals are exempt.'

PPS is a radical departure from the system of cost-based retrospective hospital reimbursement which preceded it, representing an attempt to contain costs by providing an incentive for hospitals to keep their average expenses at or below the DRG amounts. PPS appears to have been successful at slowing the increase in Medicare reimbursements for inpatient hospital services. The

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'Psychiatric, rehabilitation, alcoholanddrug dependency, long-termcare, and children's hospitals are exempt, as are psychiatric units, rehabilitation units, long-term care units, and drug and alcohol dependency units within covered hospitals.

rate of growth was 3.8 percent in 1984, compared with an annual growth rate of 10.0 percent between 1973 and 1982 (U.S. Department of Health and Human Services, 1984).[2]

Under PPS, one prominent response by hospitals to the necessity of controlling costs has been to reduce lengths of stay overall. Al though lengths of hospital stay have declined for the past fifteen years, they have fallenmore rapidly since the introduction of PPS (Guterman and Dobson, 1986). With this reduction, PPS is likely to affect the quality of post-hospital care. Some effects may be positive --for example, patients will be better off if they avoid the iatrogenic problems associated with longer stays. Conversely, the shorter lengths of stay under PPS may create adverse effects--in particular, patients who are being discharged are more ill on average than was the case previously (Coe et al., 1986). In turn, these sicker patients require more health and personal care services and more assistance with household activities (such as meal preparation) upon discharge. The necessity of caring for sicker patients has placed additional demands on the system for post-hospital care (Kornblatt, 1985; and General Accounting Office, 1987).

The possible adverse effects of PPS on the quality of post-hospital care have received extensive consideration in the media and in Congress; The Secretary of Health and Human Services (HHS) and other key HHS officials have expressed their concern about these possible effects in Congressional

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[2]This is the real rate of growth, which is the rate computed after actual dollar amounts have been adjusted for the general rate of inflation, as represented by the annual Consumer Price Index compiled by the Bureau of Labor Statistics, U.S. Department of Labor. The figures apply to fiscal years.

testimony and elsewhere.   In the Omnibus Budget Reconciliation Act (OBRA) of 1986 (P.L. 99-509), Congress mandated that the Secretary of Health and Human Services include information on the quality of post-hospital care in its annual reports to Congress on the Prospective Payment System (Section 9305i).[3] Specifically, the legislation calls for "an assessment of problems that have prevented groups of Medicare beneficiaries ... from receiving appropriate post-hospital services [as well as] an evaluation of the adequacy of the procedures for assuring quality of post-hospital services."

The current evidence on the problems associated with providing appropriate post-hospital care is largely subjective.   More objective information must be obtained to document the extent of the problems and whether they lead to adverse health outcomes for patients. If inadequate care and adverse outcomes exist, more detailed information must be obtained on the nature of problems in post-hospital care, the nature of any adverse outcomes, and the characteristics of the patients who experience such problems.   Such information is a prerequisite for developing targeted solutions.

B.   THE PURPOSE OF THE PILOT STUDY

The purpose of the pilot study was to develop, test, and refine an objective methodology for assessing the adequacy of post-hospital care in the community and the health consequences of inadequate care. The pilot study was undertaken because the methodologies that have been used in the past are

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[3]It is noteworthy that, while concern about the effects of PPS led to legislation mandating that information be collected on the quality of post-hospital care, the Congressional mandate calls for addressing the nature of current problems, not differences in the quality of post-hospital services before and after the introduction of PPS.

inadequate for addressing the concerns of the Department of Health and Human Services and the Congressional mandate.[4]

The first goal of the study was to develop a standardized approach for ensuring that the results are objective and may be generalized to the nation as a whole. The methodology that was tested and refined in the pilot study is based on standardized guidelines that specify minimally adequate post-hospital community care. These guideline specifications were compared with the care actually received by patients to identify those individuals who received care that did not meet the guidelines. This standardized approach thus' ensured that the results were objective, and that they could be generalized to the nation as a whole.

The second goal of the study was to develop a methodology that could be implemented nationally. Because an important goal of a national study is to analyze the relationship between inadequate care and adverse outcomes and because patients who experience inadequate care and suffer adverse outcomes are relatively rare, it was necessary that they be identified and oversampled. Otherwise, the size of the samples necessary for a national study would become prohibitively expensive. In addition, targeting data collection efforts towards those at high risk would minimize the total amount of burden imposed on respondents. To this end, the methodology identifies patients who are at high risk of receiving care that does not meet the guidelines and of suffering adverse outcomes.

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[4]For a discussion on the limitations of the existing methodology, see General Accounting Office (1986).

The key analyses for the pilot study focused on the validity of the guidelines, the refinement of the guidelines, and the effectiveness of procedures for identifying patients at high risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes.

C.   SCOPE OF THE PILOT STUDY

The adequacy of post-hospital community care is obviously a very broad topic. To ensure a workable design within the available resources, we defined it more narrowly.   The pilot study focused on <u>access</u> to care, rather than on the characteristics of the care provided. However, information was collected on some characteristics of care (e.g., the thoroughness of ins truc tion provided to informal caregivers). The target population for the pilot study consisted of patients who were discharged to the community (to home health care or self-care) after an acute care hospital stay.   Because the care experienced in other settings would differ, it would have been necessary to develop and test separate instrumentation and data collection procedures if, for instance, institutional settings were included; doing so was beyond the scope of this work.   Similarly, the study focused on elderly Medicare beneficiaries: because the care needs of younger, disabled Medicare beneficiaries differ to some extent, their inclusion would also have required different instrumentation and data collection procedures. Finally, the pilot study focused on nursing, therapy, follow-up physician care, and personal care.   These types of care are those most likely to be required in the immediate post-discharge period (defined here as the two weeks following discharge) and to'be affected by shorter lengths of stay. Help with household activities (such as shopping) was excluded.

D. OVERVIEW OF THE METHODOLOGY

Three primary tasks were necessary to develop a methodology for assessing the adequacy of post-hospital community care:

1. Developing guidelines that specify minimally adequate care and the adverse outcomes associated with inadequate care

2. Developing a method for identifying patients at high risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes (such patients were to be oversampled relative to their proportion in the population to obtain a sufficient sample for the analysis)

3. Developing a data collection strategy for obtaining information on patient characteristics, service receipt, and adverse outcomes

We will address each of these tasks in the following sections.

1. Develooinn the Guidelines

By "guideline," we mean a statement that defines the post-hospital community care that is minimally adequate for a patient who exhibits a specific set of characteristics. Minimal adequacy is defined as the level of care below which clinicians would anticipate a substantially increased risk of adverse outcomes. The patient characteristics that are considered in applying the guidelines are medical condition, the procedures performed on the patient in the hospital, functioning, the availability of caregivers, and care instruction provided to the patient or caregiver. We applied the guidelines by examining the patient's characteristics along these dimensions, thereby identifying which guidelines were applicable to him or her.

Guidelines were developed for 40 distinct types of care (31 types of skilled care and 9 types of semi/unskilled care), covering all common types

of post-hospital community care which are included in nursing, therapy, follow-up physician care, or personal care. Multiple guidelines (pertaining to different types of care) could apply to an individual patient. Table 1.1 lists these 40 types of care. The guidelines are presented in Appendix A.

The guidelines specify minimally adequate <u>skilled</u> care in terms of the timeliness of the initial professional visit (relative to discharge) and the total number of professional visits required in the two weeks following discharge. Other specifications not tied to professional visits were also developed, such as daily insulin injections for an insulin-dependent diabetic. The minimal level of adequate <u>semi/unskilled</u> care is typically defined in terms of the frequency with which it must be provided (e.g. , the number of times a day).

Each guideline includes a list of the adverse health outcomes that are associated with inadequate care for a particular condition. For example, the adverse outcomes for patients who require care for diabetes include hyperglycemia (high blood sugar) and unscheduled hospital readmission for a problem associated with diabetes (e.g., infection and diabetic coma}. Such measures have been called **"focused"** measures to contrast them with "global" outcome measures (e.g., functioning and mortality), which are applicable regardless of the patient's condition (Kramer et al., 1989). Focused adverse outcomes that occur up to six weeks after hospital discharge are included.

2. <u>Screening. Risk Classification. and **Sampling**</u>

The screening procedures were designed to identify those who needed **post-**hospital community care according to the guidelines. To identify those who needed <u>skilled </u>care, our screening procedures relied heavily on information

TABLE I.1

TYPES OF CARE FOR WHICH GUIDELINES HAVE BEEN DEVELOPED

Skilled Care

Diabetic Care
Amputation Care and Preprosthetic Training
Eye Care
Chest Physical Therapy
Oxygen Therapy
Aerosol Therapy
Tracheostomy Care
Monitoring Cardiopulmonary Status
Venipuncture for Blood Drawing
Blood Drawing for Protime
Medication Supervision
Intravenous (IV) Therapy, Peripheral Line
IV Therapy, Central Venous Line
Enteral Feeding
    Nasogastric tube
    Gastrostomy, jejunostomy
Dysphagia
Urinary Incontinence Management
Intermittent Catheterization
Care of Urinary Catheter
    Foley, suprapubic
    Condom catheter
    Nephrostomy tube
Bowel Incontinence Management
Ostomy Care
Wound Care
Care of Bedbound Patients
Care of Comatose Patients
Mobility Therapy for Chairbound Patients
Mobility Therapy for Impaired Ambulation
Muscle Strengthening, Flexibility, and Tone Management Exercises
    Knee surgery
    Hip surgery
    Upper extremity paralysis or fracture
Pain Management
Cast Care
Psychiatric Monitoring
Follow-Up of the Cognitively Impaired
Follow-Up Professional Monitoring

Semi/Unskilled Care

Help with Summoning Assistance (includes help with telephoning)
Help with Eating
Help with Bed/Chair Transfer
Help with Dressing
Help with Medicines
Help with Walking
Help with Bathing
Help with Toileting
Help with Meal Preparation

on medical conditions and procedures performed during the hospital stay. To identify those who needed semi/unskilled care, our screening procedures relied heavily on measures of the patient's functioning at discharge obtained from a screening interview.

The risk classification procedures pertained to the level of risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes. To identify patients at high risk of using care that did not meet the guidelines, our classification procedures relied on information on (1) the patient's living arrangement; (2) the availability of formal and informal care: (3) the patient's cognitive, emotional, and functional impairment; (4) the receipt of discharge planning: and (5) the exhaustion of informal caregivers. In addition, patients who reported unmet needs for services that led to serious health problems were assumed to be at high risk of using care that did not meet the guidelines. Patients who were physiologically vulnerable--as determined by their age, functional impairment, and severity of illness--were assumed to be at high risk of suffering adverse outcomes. Patients who reported serious health problems were also included in the group at high risk of suffering adverse outcomes. (It should be noted that these health problems are not focused outcome measures pertaining to particular conditions.)

When all the data necessary for screening and risk classification were collected, patients who needed post-hospital care (according to the screening procedures) were identified. All patients who needed post-hospital care were then classified by the level of risk of experiencing care that did not meet the guidelines and by-the level of risk of suffering adverse outcomes.

Patients at high risk of experiencing care that did not meet the guidelines **and** of suffering adverse outcomes were classified as high risk. Patients at high risk **were** selected with certainty: a random subsample of the patients not at high risk was then selected. Thus, patients at high risk were oversampled relative to their proportion in the population. All of the data necessary for applying the guidelines were collected for patients at high risk and for the random subs-ample of the patients not at high risk through additional interviews and medical records abstraction.

3. Data Sources and Measures

We implemented the data collection strategy in the pilot study to test its feasibility for a national study. The data collection strategy entailed--

o Identifying the target population

o Screening patients to identify those who needed post-hospital community care

o Classifying patients by the level of risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes

o Identifying the type of care needed by the patient, and thus the guidelines applicable to him or her

o Measuring service receipt for comparison with the guideline specifications

o Measuring outcomes, including the focused outcomes of the guidelines, and global outcomes

Figure I.1 is a flow chart of the data 'collection process. In the initial steps of the sequence, patients were deemed to be ineligible for the study if they did not meet the basic criteria for the study population or were

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FIGURE I.1

DATA COLLECTION PROCESS

| Is patient a member of study population? | NO → | Drop from study[a] |

YES ↓

| Does patient need skilled or semi/unskilled care? | NO → | Drop from study[b] |

YES ↓

| Is patient at high risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes? | NO → | Select a random subsample |
| | YES' → | Select with certainty |

| Was patient selected for sample at high risk or for sample not at high risk? | NO → | Drop from study |

YES ↓

| Identify guidelines applicable to patient |

↓

| Measure services received and compare with guideline specifications on services |

↓

| Measure services received and compare with guideline specifications on services |

↓

| Measure outcomes |

---

[a]In the pilot study, a telephone interview was administered to patients whose hospital records indicated that they were discharged to a long-term care institution. The purpose of this interview was to verify discharge to an institution, rather than to the community.

[b]In the pilot study, data were collected on a subsample of patients identified as not needing either skilled or semi/skilled care. These data were used to assess the effectiveness of the screening procedures.

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identified (via the screening procedures) as not needing either skilled or semi/unskilled care. (An exception to these exclusion rules was that data were collected in the pilot study for a subsample of patients who were identified as not needing either skilled or semi/unskilled care. These data were used to determine the effectiveness of the screening procedures.) Patients who were identified as needing skilled or semi/unskilled care were classified by the level of risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes. Patients identified as at high risk of both were sampled with certainty; a random subsample of patients identified as **not** at high risk was also selected. The remaining steps in the sequence applied only to the patients selected for the study sample. The guidelines applicable to each of these patients were identified on the basis of their characteristics. The services received by each patient in the two-week period immediately following discharge were identified and compared with the specifications for care relevant to each applicable guideline. Finally, outcomes were measured for each patient, and the focused measures of adverse outcomes were linked to each applicable guideline.

Table I.2 indicates the data sources used to address each of the seven major issues in this sequence. The data sources included:

o Hospital records, including hospital discharge records (primarily the "face" or "summary" sheet) and the full medical record of that stay

o Telephone interviews with patients and their caregivers conducted two weeks after discharge, including screening interviews and full interviews conducted if the patient was selected for the study

o Telephone interviews with patients conducted six weeks after discharge

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TABLE I.2

SOURCES OF DATA FOR THE MAJOR STUDY COMPONENTS

Component	Hospital Discharge Records	Full Hospital Records	Screening Patient/ Caregiver Interviews	Full Two-Week Patient/ Caregiver Interviews	Six-Week Patient Interviews
Identifying the Target Population[a]	.X				
Screening	X		X		
Risk Classification	X		X		
Guidelines					
Medical condition	X	X			
Other' characteristics of patient/caregiver				X	
Actual service receipt				X	
Outcomes[b]				X	X

'In the pilot study, a brief telephone interview was administered to those whose hospital records indicated that they had been discharged to a long-term care institution. The purpose of this call was to verify discharge to an institution.

[b]A national study might also rely on Medicare records to obtain data on mortality and readmissions.

Both hospital medical records and interviews had important advantages for the study ; however, each also had disadvantages. Thus, the data collection strategy combined hospital medical records and interview data, using each source when it appeared to be the best available for a particular purpose. The major advantage of hospital medical records is the level of detail of information on the patient's medical condition at discharge and on procedures performed during the hospital stay. However, other necessary information (e.g., the patient's living arrangement) is either not available in the hospital record or is not consistently available. Moreover, it is impossible to obtain hospital records and to abstract all the necessary information from them in the immediate (two-week) post-discharge period. Before research abstracting can begin, hospital records must be processed by **hospital** staff to make all the information of interest available (e.g., discharge summaries must be prepared and conditions and procedures coded). Conversely, the major advantage of interviews is that they are a good source for the types of data that are missing from hospital records, but are not a good source for medical information. In addition, measurement error associated with faulty recollection is a potential problem for some of the data (e.g., the timing of professional visits relative to discharge), particularly for longer recall periods.

As Table I.2 indicates, the data collected in the two sets of interviews (screening and full interviews) conducted two weeks after discharge were used to address a number of major issues in the study. After the screening interviews were completed, the computer automatically identified patients who needed skilled or semi/unskilled care according to the screening procedures,

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automatically classified these patients by level of risk, and automatically selected patients to be included in the study sample. If the patient was selected for the study sample, full two-week interviews were then administered to patients and caregivers.

Measures. Information on the patient's age, Medicare eligibility, and discharge destination was required to identify patients who met the basic eligibility requirements for the study. In most cases, research staff used lists of discharged patients routinely generated by the hospitals to identify patients who met these basic criteria. These lists contained coded information on the payors and discharge destination, as well as patient identifiers.

Once eligible patients were identified, the research staff obtained the face sheets of their records. ICD-9-CM codes on medical condition and procedures performed during the hospital stay were abstracted from the face sheet for all patients who met the basic eligibility criteria. These ICD-9-CM codes were used in final eligibility determination, screening, and risk classification. In particular, they were used to:

o Identify patients who were receiving treatment for end-stage renal disease. Because such patients receive Medicare benefits under a special program, they were excluded from this study.

o Identify patients whose conditions or in-hospital procedures typically require skilled care after hospital discharge

o Identify patients who were severely ill. Such patients were considered to be at high risk of adverse outcomes. (The automated Disease Staging algorithm was applied to the ICD-9-CM codes to obtain a measure of severity of illness.)

All other information necessary for screening and risk-classification was obtained from the screening interviews administered to patients and their caregivers. The screening interview with patients was the source of information on the patient's physical functioning (used to determine the need for semi/unskilled care). This interview was also the source of information on the patient's living arrangement (used in risk classification). Information on the patient's cognitive and emotional functioning and on the exhaustion of caregivers was ascertained in the caregiver screening interview.

The detailed information on the patient's medical condition, procedures performed during the hospital stay, and patient functioning (necessary for identifying the type of care under the guidelines) was abstracted from the full hospital medical record. Other information (e.g., the availability of informal services) that was necessary for this purpose was obtained in full interviews with patients and caregivers conducted two weeks after discharge for patients who were selected for the sample.

Actual service receipt was measured in the full two-week interview in terms of the number of professional visits in the two weeks after discharge, their timing relative to discharge, and whether semi/unskilled care was received at least as often as is prescribed under the guidelines. Visits of professionals to the patient's home and visits of patients to doctors' offices, clinics, and other settings to receive professional medical care were included.

Two types of outcomes were measured--focused measures that apply to specific types of patients (and, thus, to particular guidelines) and global measures that apply to patients in general. As noted earlier, the focused

outcome measures are associated with inadequate care of the condition covered by that guideline. The global outcome measures are not linked in a direct way to inadequate care. They include a broad range of measures, including mortality, functioning, and emotional well-being.

Data on a number of potential problem areas in post-hospital care were also collected in the interviews, including barriers to care (e.g., the lack of transportation and program regulations), the burden imposed on informal caregivers, deficiencies in discharge planning, the lack of care instruction to the patient or informal caregiver, and out-of-pocket costs.

E.   OVERVIEW OF ANALYSIS

The analyses conducted in the pilot study were designed to (1) test the validity of the **guidelines**; (2). identify refinements to the guidelines ; (3) test **the** effectiveness of the screening procedures; (4) test the effectiveness of the risk classification procedures: (5) develop preliminary estimates of the proportions of the elderly Medicare population in various risk groups and of the proportions experiencing care that does not meet the guidelines and of suffering adverse outcomes (so as to guide the design of a national study): and (6) assess the feasibility of the data collection procedures.

A variety of qualitative and quantitative approaches were used to analyze the validity of the guidelines and to provide a basis for their refinement. These approaches complemented each other, allowing us to examine whether the results of one approach were consistent with the results of the others. The analyses performed to assess the validity of the guidelines and to identify guidelines that required refinement **included:**

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o A clinical case-by-case review of 100 specially selected records (reported on elsewhere)

o A comparison of the likelihood of adverse outcomes when care met and did not meet the guidelines, based on cases for whom we had medical records abstracts, two-week interview data, and six-week interview data

o A comparison of hospital discharge orders with care specified under the guidelines, based on cases for whom we had medical records abstracts and two-week interview data

An analysis of the effectiveness of the screening procedures compared the need for care according to the screening procedures with the need for care according to the guidelines, so as to identify (1) patients erroneously screened out as not needing care who in fact did need care under the guidelines; and (2) patients erroneously screened in as needing care who needed no care under the guidelines. Both types of cases were reviewed to identify refinements to the screening procedures. The analysis of the risk classification procedures compared the incidence of care that did not' meet the guidelines and of adverse outcomes for patients at high risk and not at high risk to determine whether patients identified as at high risk were in fact more likely to experience care that did not meet the guidelines and to suffer adverse outcomes.

The experience of the pilot study was reviewed to assess the feasibility of the data collection strategy and to suggest refinements to it.

Finally, the pilot study data were used to develop preliminary estimates of the percentage of elderly Medicare patients at different risk levels who experienced care that did not meet the guidelines and who suffered adverse outcomes. By reweighting to correct for oversampling, preliminary estimates for the elderly Medicare population as a whole were developed.

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F. OVERVIEW OF REPORT

Following a detailed description of the guidelines and their development in Chapter II, this report describes the results of the test of the pilot study methodology and the recommended refinements to that methodology. Chapter III presents the analysis of the likelihood of adverse outcomes when care met and did not meet the guidelines. Chapter IV presents an analysis of the effectiveness of the screening and risk classification procedures at identifying those who needed post-hospital community care and to classify them by the level of the risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes. Chapter V presents the analyses of other issues, including (1) a comparison of care ordered (according to hospital records) with care specified under the guidelines; and (2) an assessment of the feasibility of the data collection strategy. Chapter VI presents our conclusions.

There are three appendices. Appendix A presents the guidelines. Appendix B discusses various technical issues not covered in-depth in the body of the report. Appendix C presents preliminary estimates of the percentages of Medicare patients who used care that did not meet the guidelines and who suffered adverse outcomes.

II. GUIDELINES MEASURING THE ADEQUACY OF POST-HOSPITAL COMMUNITY CARE

As indicated in Chapter I, the guidelines are designed to specify the post-hospital community care that is required by patients with different types of care needs in order to prevent adverse health outcomes. It is important to stress that the guidelines are **not** intended to define good clinical practice. To the extent that good clinical practice exceeds minimally adequate care, the former is not a good yardstick for our purposes.

The guidelines are a model. As with all models, tension exists between keeping the guidelines simple enough to be workable and creating additional guidelines (or subdividing existing guidelines) to deal with patients who exhibit somewhat different characteristics. The guidelines would be too complex if we tried to specify minimally adequate care under **all** conditions, including relatively rare ones. Thus, our goal has been to develop guidelines which specify minimally adequate care in the overwhelming majority (roughly 80 percent) of cases. While such simplicity is necessary, it inevitably leads to some error. Where we could not eliminate error, we have tried to err by understating the extent both of care that does not meet the guidelines and of adverse outcomes.

In this chapter, we describe our approach to the guidelines and the process of developing them. (As noted in Chapter I, the guidelines are presented in Appendix A.)

A.   THE GUIDELINES

The key issues in designing the guidelines included the types of care to be covered, the aspects of care to be taken into account in defining adequacy, and the types of outcomes to be included. We consider each of these issues in turn below.

1.   **Types** of Care Covered

The guidelines are designed to cover professional care in all community settings, including care provided in a patient's home and in a physician's office or clinic.

The guidelines are designed to consider the types of care that are important in the two-week period immediately after discharge and that are likely to be affected by shorter hospital stays. While the choice of the **two-**week period immediately after discharge is somewhat arbitrary, our focus on the immediate post-discharge period flows from the fundamental problem which this study seeks to address--that is, whether Medicare beneficiaries have difficulty in obtaining adequate post-hospital care when hospital services are paid for on a prospective basis. We expect that such effects will occur (if they occur at all) primarily through the effect of shorter hospital stays and the associated tendency for patients to be more' seriously ill at discharge.

Patients who are more ill at discharge are likely to need more nursing, therapy (physical therapy or respiratory therapy), and personal care. Consequently, the guidelines focus on these types of care. The types of care which are not likely to be affected by the patient's condition upon discharge are beyond our mandate. For example, the need for assistance in locating and moving to a suitable dwelling is unlikely to be affected by a difference in

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length of stay. In addition, for many types of patients, professional **follow-**up (for example, from a physician) is not necessary during the first two weeks after discharge. Thus, we have developed guidelines for professional supervision only for the types of patients who require such assistance in the first two weeks after discharge.

Because inadequate care may ultimately be defined in terms of adverse outcomes, we focus on the types of care for which inadequate care in the two weeks after discharge may be expected to lead to serious adverse outcomes (for some portion of the patients who experience inadequate care). Outcomes that' most persons would agree are of a serious medical nature were considered in determining whether a guideline should be developed for a given type of care (for example, unscheduled hospital readmissions, emergency room or physician visits for'unexpected problems, and various clinical measures of morbidity). We excluded types of care which may be desirable, and even necessary, but for which a delay in receipt beyond the first two weeks is unlikely to lead to adverse health outcomes. For example, a delay in the receipt of speech therapy beyond the first two weeks is unlikely to lead to adverse outcomes. This focus on serious adverse health outcomes is consistent with our goal of defining **minimally** adequate care.

The guidelines cover both formal and informal care (that is, care provided by family members and friends). The care provided by informal caregivers is very important. Informal caregivers of the elderly are a major source of assistance with personal care and household activities and are clearly important in the **immediate** post-discharge period. In addition to their provision of semi/unskilled care, **it** is common practice for family

members to be trained to provide routine medical treatments, such as administering insulin injections. Such training may be provided in the hospital or following discharge. Because family members are typically relied on to provide routine medical treatments, we did not ignore them in developing guidelines for skilled care. Where such routine medical treatment met our criteria of importance in the immediate post-discharge period and the possibility of suffering serious adverse health outcomes, we included it in the guidelines.

In developing the guidelines, we excluded treatments that are rarely provided in the community. As discussed in Chapter I, the goal of a national study is to assess the adequacy of post-hospital community care on a nationwide basis. Given this purpose, measuring the adequacy of treatments that are rarely provided in community settings is not justified. The expenditure of resources required to develop and test the guidelines is unwarranted in these cases. Examples of such treatments include peritoneal dialysis and the care of respirator-dependent patients.'

A few other types of care were considered but excluded. Hospice counseling and support were eliminated because they are too variable to permit developing specifications for care. End-stage renal disease (ESRD) patients were excluded because a special program is available to them, and the adequacy of their care under PPS is not an issue. Given that these patients were excluded, we have not developed guidelines involving renal dialysis.

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[1]However, we did include questions in the two-week interview to ascertain whether any patients in the pilot study were receiving these two types of treatments and whether they had experienced problems with them.

2. **Aspects** of Care Associated with **Adequacy**

The guidelines focus on _access_ to appropriate care. The focus on access was necessitated by the data sources available for a national study. The patient and proxy interviews are our only source of information on **post-**hospital care. Clearly, patients and their proxies are not able to provide an accurate, detailed description of the n<u>ature </u>of the care provided to them, so that one might judge whether it conforms to prespecified standards of quality.

Given that we wish to study access to appropriate care, what aspects of care are relevant7 We determined that two aspects are critical: first, that services be provided in a timely way and, second, that they be provided in sufficient quantity.

Quantity is central to access to appropriate post-hospital care. If multiple episodes of care are required but are not received, care is clearly inadequate. Moreover, specifying a minimum number of episodes of care for patients with a given set of characteristics **is** objective and easy to understand.

The guidelines for skilled care specify the total number of professional visits necessary for minimally adequate care in the two-week post-discharge period. For two reasons, no distinction is made between the types of professionals whom the patient sees in the visit. First, in many cases, one type of professional may **substitute** for another type. For example, a nurse or a physician may monitor the cardiopulmonary status of a patient. Second, data on the receipt of professional visits are self-reported. Some patients are not able to discriminate accurately between the different types of

professionals.   For example, a patient might have great difficulty in discriminating between a nurse and a physical therapist. Thus, because we determined that the potential for measurement error was too great, we did not pursue collecting data on visits by types of professional.

For care that may be provided by informal caregivers, episodes of care do not necessarily correspond to visits, and the approach used for professional care is not workable.   Instead, the guidelines specify the daily frequency with which specific types of care are required. For example, they specify **that** `insulin-dependent` diabetics receive insulin injections daily, and that a person impaired in dressing is to have assistance in changing clothes at least once daily.

Another issue in developing guidelines in terms of the quantity of care is that a minimum frequency cannot be specified for some types of care. In these cases, the guidelines specify that the care is to provided as ordered **(e.g.,** help with medications) or as necessary (e.g., help with transferring).

The guideline specifications for the timeliness of professional visits are expressed in terms of the longest acceptable delay for the initial professional visit after hospital discharge. We have not attempted to specify a schedule for professional visits after the initial visit because the timing of successive visits depends on what is learned about the patient at the initial visit, and we have no information about any changes in the patient's condition after his or her discharge.

Another approach was used to develop specifications on the timeliness of care for which the skills of a professional are not necessarily required. Because such care may be provided by persons who live in the same household

as the patient, the concept of the initial visit is not workable. Rather, the **guidelines** specify the maximum delay acceptable in the receipt of services. Examples include the guidelines which require that no delay be experienced in summoning help in an emergency, and that no more than three doses of intravenous (IV) antibiotics be missed before an IV-line can be reinserted. In contrast to the timeliness of professional visits, these guidelines on delay apply to the entire two-week period.

3. <u>Outcomes</u>

The guidelines are designed to specify care that is minimally adequate to prevent adverse outcomes. The outcome measures associated with each guideline are limited to those adverse outcomes that clinicians would anticipate if care on that guideline were inadequate. To make the link between inadequate care and adverse outcomes as clear as possible, the guidelines include only those adverse outcomes which are linked to inadequate care through well-known clinical processes.

Outcome measures applicable only to patients who need particular types of care have been called "focused' outcome measures (Kramer et al., 1989). In contrast, "global" outcome measures are applicable to patients in general. Global measures of outcomes, which are applicable to all patients and all guidelines, were also included in the pilot study instruments but not analyzed here. Because they are not clearly linked to the inadequacy of a particular type of care, these global outcomes were not used to test the guidelines in the pilot study.

The focused outcome measures linked to each guideline are of two general types. One type pertains to morbidity--that is, complications or the

exacerbation of a condition associated with the inadequacy of each type of care. Examples include an infection at the site of an IV or a fall by a patient who is impaired in transfer. The other type pertains to the unscheduled and unexpected use of health care services (readmission to the hospital, admission to a nursing home, visits to an emergency room or urgent care center, and visits to a physician's office or clinic) for a complication or exacerbation of a condition associated with the inadequacy of the type of care covered by a guideline.;

Most of the morbidity outcomes included in the guidelines that are due to inadequate care in the two weeks immediately following discharge are likely to occur immediately. Therefore, we measured these morbidity outcomes during the two weeks following discharge. The exceptions are contractures and decubitus, which may take longer to appear. They were measured during weeks three through four following discharge. Depression was measured at the time of the six-week interview. We did not include a measure of depression two weeks after discharge because many patients may be temporarily depressed after their discharge and because depression scales are rather lengthy. The administration of the screening and full two-week interviews places a substantial burden on respondents without the inclusion of a lengthy depression measure.

All the outcomes on the unexpected use of health services were measured for weeks one through four following discharge. In addition, readmission to a hospital and admission to a nursing home were measured for weeks five through six following discharge.

B. DEVELOPING THE GUIDELINES

The guidelines were developed on the basis of staged clinical input.

1. Drafting

The initial drafts for the skilled care guidelines were developed for one profession at a time. Barbara W. Schneider, M.A., R.N., worked individually with a nurse, a physical therapist, and a respiratory therapist (each of whom had extensive community-care experience) to compile an exhaustive list of the various types of care provided by each of these professions and to specify initial levels of minimally adequate care. The initial consultants are listed in Table 11.1. These early drafts were quite detailed, particularly in terms of the patient characteristics associated with each type of care and the differences between in-home and outpatient care. While these early drafts were probably too detailed to be workable, having detailed guidelines for an exhaustive list of types of care helped ensure that important issues were not overlooked.

Draft guidelines for semi/unskilled care were developed by project staff.

The initial drafts of the guidelines were reviewed by a advisory panel consisting of clinicians and researchers from a variety of backgrounds. The members of this panel are listed in Table II .2. They evaluated the feasibility of the overall approach to the guidelines and suggested a number of revisions. These revisions focused on simplifying the guidelines and on addressing issues associated with the adequacy of post-hospital care which were not amenable to the guideline approach.

The early drafts were then revised extensively by a group at Boston University, consisting of three physicians and a nurse and headed by Dr.

TABLE II.1

INITIAL CONSULTANTS

Dr. Laurie **Hach**

Philadelphia Institute for Physical Therapy
Philadelphia, Pennsylvania

Ms.Betsy Solan

Formerly of the Visiting Nurse Association of
  Middlesex County, New Jersey

Ms. Ann **Leitzinger**

Head, Respiratory Therapy Department
Miles Medical Hospital
Damariscotta, Maine

TABLE II.2

COMBINED TECHNICAL AND CLINICAL ADVISORY **PANELS**

Dr. John Burton

Director, Division of Geriatrics
Francis Scott Key Medical Center
Johns Hopkins University
Baltimore, Maryland

Dr. **Merilyn** Coe

Northwest Oregon Health Systems
Beaverton, Oregon

Ms. Marie Fraser

Vice-President for Patient Care Services
  Community Home Health Services
Philadelphia, Pennsylvania

Dr. **Lisa Iezzoni**

Health Care Research Unit
Boston University Medical Center
Boston, Massachusetts

Dr. Kenneth Kahn

Board Member, American Medical Peer Review Association
Association Medical Director, Colorado Foundation for
  Medical Care Review Programs
Boulder, Colorado

Ms. June Simmons

Director, Senior Care Network and Patient Services
Hunting Memorial Hospital
Pasadena, California

Ms.Mary Walsh

Professor of Nursing, Catholic University
Project Director, Robert Wood Johnson Foundation
Teaching Nursing Home Project
Washington, D.C.

Knight Steel. The other members of the group were Dr. Jeremiah Kelly, Dr. Lawrence Markson, and Ms. Margaret Polito. Ms. Schneider worked with the Boston University group to simplify the guidelines and to integrate them across professions, types of patients, and settings. The types of care provided to patients who exhibit the same characteristics were combined into single guidelines, and in-home and outpatient care were combined. Distinctions between professions were minimized when doing so was justified. The group also reviewed the prescriptions of minimal care and developed lists of adverse health outcomes that would be likely to occur if care were inadequate.

The clinical members of the initial advisory panel, supplemented by two other clinical consultants, served as a clinical advisory panel who reviewed drafts of the guidelines as revised by the Boston University group.* The members of the clinical advisory panel are listed in Table 11.3.

2. Pretesting

The guidelines were pretested to assess the validity of the specifications for minimally'adequate care. The pretest was conducted by the Boston University group for a sample of 50 patients from the Boston University Home Medical Service (HMS). These patients had been hospitalized recently at Boston University Medical Center.

During the pretest, a nurse or a physician abstracted each patient's hospital record using the medical record abstract form designed for this

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*This clinical advisory panel **also** reviewed the approach for screening and classifying patients by the level of risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes.

TABLE 11.3

CLINICAL PANEL

Ms. Linda **Berezney**

Partner, Berezney and Luebble Physical Therapy
Former Director of Clinical Services
Orange County Visiting Nurse Association
Orange County, California

Dr. **John** Burton

Director, Division of Geriatrics
Francis Scott Key Medical Center
Johns Hopkins University
Baltimore, Maryland

Ms. Marie Fraser

Vice-President, Patient Care Services for
  Community Home Health Services
Philadelphia, Pennsylvania

Ms. Yvette Luque

President, Visiting Nurse Association
Los Angeles, California

Ms. June Simmons

Director, Senior Care Network and Patient Services
Hunting Memorial Hospital
Pasadena, California

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study. Because these pretest patients did not have two-week interviews, a special form was designed to collect similar information from the patient's HMS record. The guidelines were applied manually to the abstracted data for each case.

The amount of care specified by the guidelines was reviewed by two physicians--the patient's attending physician at HMS and a research physician (also from HMS) who had not seen the patient but who had reviewed the hospital record, evaluated post-hospital care needs on that basis, and made a judgment about the minimal adequacy of the care specified by the guidelines applicable to that patient.

Both types of physicians were asked to rate the guideline-specified care as one of the following:

o Less than minimally adequate to prevent adverse health outcomes

o Minimally adequate to prevent adverse health outcomes

o More than minimally adequate to prevent adverse health
      outcomes

If they considered the care specified by the guidelines to be less or more than minimally adequate, the physicians were also asked to comment on the reasons for their conclusion.

Sixty-two percent of the physician ratings in the pretest indicated that the guidelines represented minimally adequate care. Those that did not fall into this category were divided evenly between "less than minimally adequate" and "more than minimally adequate. " These results suggested that, as a group, the guidelines did define minimally adequate care to a first approximation and were not grossly under- or overstating the amount of care required.

Cases with ratings of more or less than minimally adequate care were reviewed individually to identify refinements to the guidelines. These refinements were reviewed and adopted by the clinical advisory panel.

III.   ADVERSE OUTCOMES WHEN **CARE** MET AND DID NOT MEET THE GUIDELINES

The guidelines are designed to define the levels of care that are minimally adequate to prevent adverse health outcomes. If, taken as a group, the guidelines provide a valid definition of minimally adequate care, we expect that substantially more adverse outcomes will be experienced when care does not meet the guidelines than when it does. The analysis described in this chapter compares the likelihood of adverse outcomes when care meets and does not meet the guidelines, so as to assess the validity of the guideline specifications of minimally adequate care.

Hereafter in this chapter, we use the term <u>Basic Guidelines</u> to refer to the guidelines as developed by the clinical consensus panel. This definition permits us to distinguish them from the variants of the guidelines that are also discussed in this chapter. These variants were developed to test the sensitivity of our results to different assumptions about the specifications for minimally adequate care.

The chapter begins with a discussion of the characteristics of the pilot study data, the sample, the unit of analysis, and the estimation technique. We then present results which compare the likelihood of adverse outcomes when care met and did not meet the guideline specifications under the Basic Guidelines and under its variants.

A.   CHARACTERISTICS OF THE PILOT STUDY DATA ON THE GUIDELINES

To the extent that the data collected in the pilot study do not represent the breadth of conditions included in the guidelines, it would be less appropriate to consider this analysis as validating the guidelines <u>as a **group**</u>.

Furthermore, to the extent that we do not observe adverse outcomes and care that does not meet the guidelines across the breadth of conditions, our comparison of adverse outcomes when care met and did not meet the guidelines will not reflect the validity of guidelines as a group.

Tables III.1 and III.2 present the distributions of the skilled and semi/unskilled guidelines applicable in the pilot study data under the Basic Guidelines. As Table III.1 indicates, all of the semi/unskilled guidelines are represented, and there is no marked concentration of observations on particular guidelines. As Table III.2 indicates, all but 7 of the skilled care guidelines are represented. Those not represented are Chest Physical Therapy (13), Tracheostomy Care (16), Nasogastric Tube (30), Condom Catheter (29), Nephrostomy Tube (30), Care of Comatose Patients (35), and Upper Extremity Paralysis (40). These exclusions do not appear to be serious, especially given that some catheter guidelines are included (even though condom catheters and nephrostomy tubes are not), and that some guidelines for conditions which require muscle strengthening (e.g., hip surgery) are included, even though upper extremity paralysis is not. In contrast to semi/unskilled care, there is a marked concentration of observations on one skilled guideline. About one-third of all the observations on skilled guidelines involve the Medication Supervision Guideline. The remaining two-thirds are not particularly concentrated.

Tables III.3 and III.4 present the distributions of observations that did not meet the guidelines under the Basic Guidelines for semi/unskilled and skilled care, respectively. The distribution of observations that did not meet the semi/unskilled guidelines is not concentrated in individual guidelines; however, care met the guideline on eating in every case and met

TABLE III.1

APPLICABLE GUIDELINES UNDER THE BASIC GUIDELINES:
SEMI/UNSKILLED CARE

Guideline	Number	Percent
Help with summoning assistance (1)	41	4.71
Help with eating (2)	36	4.14
Help with bed/chair transfer (3)	75	8.62
Help with dressing (4)	152	17.47
Help with medicines (5)	159	18.28
Help with walking (6)	70	8.04
Help with bathing (7)	102	11.72
Help with toileting (8)	80	9.20
Help with meal preparation (9)	155	17.82
TOTAL	870	100.00

NOTE: The numbers in parentheses refer to the guideline number.

TABLE III.2

APPLICABLE GUIDELINES UNDER THE BASIC GUIDELINES:
SKILLED CARE

Guideline	Number	Percent
Diabetic Care (10)	13	3.04
Amputation Care (11)	3	0.70
Eye Care (12)	2	0.47
Chest Physical Therapy (13)	0	--
Oxygen (14)	4	0.93
Aerosol Therapy (15)	16	3.74
Tracheostomy Care (16)	0	--
Monitoring Cardiopulmonary Status (17)	29	6.78
Venipuncture (18)	26	6.07
Coumadin Monitoring (19)	13	3.04
Medication Supervision (20)	147	34.34
IV Antibiotics and Chemotherapy (peripheral line) (21)	2	0.47
IV Pain Medication (peripheral line) (22)	2	0.47
IV Therapy (central venous line) (23)	2	0.47
Nasogastric Tube (24)	0	--
Gastrostomy, Jejunostomy (25)	1	0.23
Dysphagia Management (26)	1	0.23
Urinary Incontinence Management (27A)	5	1.17
Intermittent Catheterization (27B)	1	U.23
Foley, Suprapubic Catheter (28)	6	1.40
Condom Catheter (29)	0	--
Nephrostomy Tube (30)	0	--
Bowel Incontinence Management (31)	2	0.47
Ostomy Care (32)	3	0.70
Wound Care (33)	13	3.04
Care of Bedbound Patients (34)	6	1.40
Care of Comatose Patients (35)	0	--
Mobility Therapy for Chairbound Patients (36)	14	3.27
Mobility Therapy for Impaired Ambulation (37)	21	4.91
Knee Surgery (38)	6	1.40
Hip Surgery (39)	4	0.93
Upper Extremity Paralysis (40)	0	--
Pain Management (41)	36	8.41
Cast Care (42)	1	0.23
Psychiatric Monitoring (43)	3	0.70
Follow-up of the Cognitively Impaired (44)	6	1.40
Follow-up of Professional Monitoring (45)	40	9.34
TOTAL	428	100.00[a]

NOTE: The numbers in parentheses refer to the guideline number.

[a]Does not add to 100 percent due to rounding.

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TABLE III.3

CARE THAT DID NOT MEET BASIC GUIDELINES:
SEMI/UNSKILLED CARE

| Guideline | Observations in Which Care Did Not Meet Guidelines | | Total[a] |
	Number	Percent	Observations
Help with summoning assistance (1)	3	7.32	41
Help with eating (2)	0	--	36
Help with bed/chair transfer (3)	4	5.33	75
Help with dressing (4)	8	5.26	152
Help with medicines (5)	6	3.77	159
Help with walking (6)	3	4.28	70
Help with bathing (7)	3	2.94	102
Help with toileting (8)	1	1.25	80
Help with meal preparation (9)	8	5.16	155
TOTAL	36	4.14	870

NOTE: The unit of observation is each applicable guideline. The numbers in parentheses refer to the guideline number.

[a]Includes observations for which data on the adequacy of care are missing.

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TABLE III.4

CARE THAT DID NOT MEET BASIC GUIDELINES:
SKILLED CARE

Guideline	Observations in Which Care Did Not Meet Guidelines		Total[a] Observations
	Number	Percent	
Diabetic Care (10)	10	**76.92**	13
Amputation Care **(11)**	2	66.67	3
Eye Care (12)	2	100.00	2
Chest Physical Therapy (13)	--	--	0
Oxygen (14)	4	100.00	4
Aerosol Therapy (15)	14	87.50	16
Tracheostomy Care (16)	--	—	0
Monitoring Cardiopulmonary Status (17)	16	55.17	29
Venipuncture (18)	1	3.85	26
Coumadin Monitoring (19)	8	61.54	13
Medication Supervision (20)	29	19.73	147
IV Antibiotics and Chemotherapy (peripheral line) (21)	2	100.00	2
IV Pain Medication (peripheral line) (22)	2	100.00	2
IV Therapy (central venous line) (23)	1	50.00	2
Nasogastric Tube (24)	--	--	0
Gastrostomy, Jejunostomy (25)	1	100.00	1
Dysphagia Management (26)	1	100.00	1
Urinary Incontinence Management **(27A)**	1	20.00	5
Intermittent Catheterization (27B)	0	0.00	1
Foley, Suprapubic Catheter (28)	3	50.00	6
Condom Catheter (29)	--	—	0
Nephrostomy Tube (30)	--	--	0
Bowel Incontinence Management (31)	0	0.00	2
Ostomy Care (32)	2	66.67	3
Wound Care (33)	11	84.62	13
Care of **Bedbound** Patients (34)	5	83.33	6
Care of Comatose Patients (35)	—	--	0
Mobility Therapy for Chairbound Patients (36)	8	57.14	14
Mobility Therapy for Impaired Ambulation (37)	16	76.19	21
Knee Surgery (38)	3	50.00	6
Hip Surgery (39)	3	75.00	4
Upper Extremity Paralysis (40)	--	--	0
Pain Management (41)	18	50.00	36
Cast Care (42)	0	0.00	1
Psychiatric Monitoring (43)	1	33.33	3
Follow-up of the Cognitively Impaired (44)	3	50.00	6
Follow-up of Professional Monitoring (45)	12	30.00	40
TOTAL	179	41.82	428

NOTE: The unit of observation is each applicable guideline. The numbers in parentheses refer to the guideline number.

[a]Includes observations for which data on adequacy of care are missing.

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the guideline on toileting in every case but one. Care met the guideline specifications in every case for three skilled care guidelines, including intermittent catheterization, bowel incontinence management, and cast care. The distribution of observations in which care did not meet skilled care guidelines is less concentrated than the distribution of conditions on the skilled care guidelines. About 16 percent of the observations in which care did not meet the guidelines are for the Medication Supervision Guideline, compared with about one-third of all observations on skilled care conditions.

Table III.5 and III.6 present the distributions of observations with adverse outcomes under the Basic Guidelines for semi/unskilled and skilled care, respectively. As Table III.5 indicates, adverse outcomes were not specified for three semi/unskilled guidelines--those for summoning assistance, dressing, and bathing. Although outcomes were specified, we observed **none** for meal preparation. In addition, **almost** half of the adverse outcomes we observed are for toileting. As Table III.6 indicates, there is also some concentration among the observations on adverse outcomes for skilled care. We observed adverse outcomes for slightly more than half of the guidelines on which we have observations, and one-third **(16/49)** of the observations are for the Pain Management Guideline.

Based on this evidence, we conclude that the pilot study data represent the breadth of the guidelines reasonably well in terms of conditions and care that do not meet the guidelines (although the Medication Supervision Guideline is problematic). The adverse outcomes observed reflect the breadth of the guidelines less well, with adverse outcomes concentrated in the Help with Toileting and Pain Management guidelines. One must focus particularly on the three problematic guidelines (toileting, pain management, and medication supervision) as our results are interpreted.

TABLE 111.5

ADVERSE OUTCOMES UNDER THE BASIC GUIDELINES:
SEMI/UNSKILLED CARE

| Guideline | Observations with Adverse Outcomes | | Total[b] |
	Number	Percent	Observations
Help with summoning assistance (1)	a	a	41
Help with eating (2)	1	2.78	36
Help with bed/chair transfer (3)	8	10.67	75
Help with dressing (4)	a	a	152
Help with medicines (5)	2	1.26	159
Help with walking (6)	10	14.28	70
Help with bathing (7)	a	a	102
Help with toileting (8)	20	25.00	80
Help with meal preparation (9)	0	0.00	155
TOTAL	41	4.71	870

NOTE: The unit of observation is each applicable guideline. The numbers in parentheses refer to the guideline-number.

[a]No adverse outcomes were specified.

[b]Includes observations for which data on the adverse outcomes are missing.

TABLE III.6

ADVERSE OUTCOMES UNDER THE BASIC GUIDELINES:
SKILLED CAKE

| Guideline | Observations With Adverse Outcomes | | Total[a] |
	Number	Percent	Observations
Diabetic Care (10)	6	46.15	13
Amputation Care (11)	2	66.67	3
Eye Care (12)	0	0.00	2
Chest Physical Therapy (13)	--	--	0
Oxygen (14)	0	0.00	4
Aerosol Therapy (15)	1	6.25	16
Tracheostomy Care (16)	--	--	0
Monitoring Cardiopulmonary Status (17)	1	3.45	29
Venipuncture (18)	1	3.85	26
Coumadin Monitoring (19)	1	7.69	13
Medication Supervision (20)	4	2.72	147
IV Antibiotics and Chemotherapy (peripheral line) (21)	0	0.00	2
IV Pain Medication (peripheral line) (22)	0	0.00	2
IV Therapy (central venous line) (23)	0	0.00	2
Nasogastric Tube (24)	--	--	0
Gastrostomy, Jejunostomy (25)	0	0.00	1
Dysphagia Management (26)	0	0.00	1
Urinary Incontinence Management (27A)	0	0.00	5
Intermittent Catheterization (27B)	0	0.00	1
Foley, Suprapubic Catheter (28)	0	0.00	6
Condom Catheter (29)	--	--	0
Nephrostomy Tube (30)	--	--	0
Bowel Incontinence Management (31)	0	0.00	2
Ostomy Care (32)	1	33.33	3
Wound Care (33)	1	7.69	13
Care of Bedbound Patients (34)	2	33.33	6
Care of Comatose Patients (35)	--	--	0
Mobility Therapy for Chairbound Patients (36)	6	42.86	14
Mobility Therapy for Impaired Ambulation (37)	4	19.05	21
Knee Surgery (38)	1	16.67	6
Hip Surgery (39)	1	25.00	4
Upper Extremity Paralysis (40)	--	--	0
Pain Management (41)	16	44.44	36
Cast Care (42)	0	0.00	1
Psychiatric Monitoring (43)	0	0.00	3
Follow-up of the Cognitively Impaired (44)	1	16.67	6
Follow-up of Professional Monitoring (45)	0	0.00	40
TOTAL	49	11.45	428

NOTE: The unit of observation is each applicable guideline. The numbers in
        parentheses refer to the guideline number.

[a]Includes observations for which data on adverse outcomes are missing.

B. UNITS OF ANALYSIS AND SAMPLES

We used each applicable guideline (rather than the patient) as the unit of analysis. We did so because the link between adverse outcomes and care that does not meet the guidelines is not strictly defined when the patient rather than the guideline is the unit of analysis, since multiple guidelines may apply to the same patient. In particular, if a patient experiences care that does not meet the specifications of **any** of the guidelines that apply to him or her, he or she would be treated as having experienced care that did not meet the guidelines. Similarly, if a patient suffers adverse outcomes on **any** of the guidelines that apply to him or her, he or she would be treated as suffering an adverse outcome. Consequently, **"cross-overs"** are possible when the patient is the unit of analysis. That is, a patient may be treated as experiencing care that does not meet the guidelines and as suffering an adverse outcome even though the failure to meet the guideline specifications occurred for one guideline and the adverse outcome was associated with another guideline.

Some cross-over cases probably represent situations in which the inadequacy of care and adverse outcomes are truly linked at the level of the individual guideline, despite the fact that they are not linked in the analysis. For example, consider the case of a patient to whom the meal preparation and mobility therapy guidelines are applicable. This patient would report not having regular meals due to the inadequacy of help with meal preparation, and would also report suffering a fall, which is an adverse outcome for the mobility therapy guideline (for which the guideline specifications were met). It is highly possible that the fall was due to a general problem of the inadequacy of help with personal care which surfaced

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as a failure to meet the guideline on meal preparation rather than the guideline on mobility.

While we can refine the individual guidelines to improve the linkage between care that does not meet the guidelines and adverse outcomes, the linkage will never be perfect. Even with refined guidelines, cases will likely exist for which a failure to meet the guidelines and adverse outcomes are truly linked but the linkage is not reflected in the individual guidelines.[1] After all, the guidelines represent simple models of complex relationships.

The possible existence of subtle linkages that are not captured in individual guidelines but are captured for the patient suggests that results based on each applicable guideline as the unit of analysis probably understate the strength of the relationship between inadequate care and adverse outcomes. Because it captures subtle relationships that are not reflected in the data on individual guidelines, using the patient as the unit of analysis eliminates this source of understatement. Unfortunately, using the patient as the unit of analysis also treats cross-over cases that are **not** linked (even **in subtle** ways) as if they were linked and, thus, overstates the relationship between inadequate care and adverse outcomes. We have no way to know the relative sizes of the over- and understatement. Due to the potential for overstatement when the patient is the unit of analysis, our analysis of the likelihood of adverse outcomes **relied on** each applicable guideline as the unit of analysis.

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[1] Of course, cases will also certainly exist for which inadequate care and adverse outcomes are truly linked but the linkage is not captured at either the guideline or the patient level.

1. Sample Sizes

The analysis of the likelihood of adverse outcomes required that we apply the guidelines to determine whether the patient experienced care that did not meet the guidelines and suffered adverse outcomes. Applying the guidelines and determining whether they were met required information from the full medical record (recorded on the medical record abstract form) and the full two-week interview. Information on the presence of adverse outcomes came from two sources: the two-week interview (for outcomes during weeks one and two following discharge) and the six-week interview (for outcomes during weeks three through six following discharge). The medical record abstract form and two-week interview were completed for 299 eligible patients. The medical record abstract form, two-week interview, **and** six-week interview were completed with 240 **patients.**[2] The samples for this analysis were selected on the basis of the data collected on these 299 or 240 patients. Consequently, the sample sizes vary according to the follow-up time period involved. (Appendix B presents a discussion of the sample design.)

However, because multiple guidelines could apply to the same patient and because we used each applicable guideline as the unit of analysis, the sample

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[2]**For** two reasons, the sample for the six-week interview was intentionally smaller than the two-week interview sample. First, cases identified in the screen as needing no care were excluded from the six-week interview sample. These cases were to be used to compare care needs based on the screen with care needs based on the guidelines, and six-week interview data were not required for this purpose. Second, the two-week interview sample was larger than originally intended, due to the fact that the risk classification procedures were revised because they appeared to be identifying too large a portion of the population as at high risk. Some patients who were originally classified as at high risk (for whom two-week interviews had already been completed) were reassigned to the not-at-high-risk group. In this situation, the two-week interview sample had to be enlarged to retain the statistical power of the original design. Rather than enlarge the six-week interview sample to correspond to the larger two-week interview sample, we designed the six-week interview sample to retain the power of the original design. (See Appendix B for further discussion on the sample.)

sizes for this analysis are larger than the samples of patients. On average, 4.3 guidelines apply to each patient in the pilot study sample. It should be noted, however, that the sample sizes vary according to the type of care (skilled care, semi/unskilled care, and all care) that was considered.

Table III.7 presents sample sizes for different types of care and different follow-up periods using each applicable guideline as the unit of analysis. For example, for the analysis of skilled care in weeks one through two, a sample of 381 observations is available.

In our analysis, we focused on the estimates of the likelihood of adverse outcomes for weeks **one** through six--that is, for estimates which combined the follow-up periods. We combined them because only a small minority (14 percent) of adverse outcomes occur in weeks three through six. Therefore, an extensive, separate analysis of the two time periods was unwarranted.

The sample sizes for weeks one through six using each applicable guideline as the unit of analysis were formed on the basis of information for all patients who had medical records abstract and two-week interview data. Fifty-nine of these patients did not have six-week interview data, and thus had no six-week outcome measures. We used the presence of an adverse outcome in weeks one through two as their. measure of adverse outcomes. Thus, we implicitly assumed that those patients who had no adverse outcomes in weeks one through two also had none in weeks three through six. This implicit assumption leads to an understatement of the incidence of adverse outcomes. However, the overall incidence of adverse outcomes during weeks three through six is low relative to the overall incidence in weeks one through two, and the understatement is slight.

TABLE III.7

SAMPLE SIZES FOR AN ANALYSIS OF THE BASIC GUIDELINES

Time Period	Semi/Unskilled Care	Skilled Care	All Care
Weeks One through Two	366	381	747
Weeks Three through Six	363[a]	315[a]	678[a]
Weeks One through Six	368[b]	373[b]	741[b]

NOTE: The unit of analysis is each applicable guideline. Sample sizes under the variants differ due to the inapplicability of some guidelines under some variants and due to missing data, which precluded determining whether the specifications for some variants were met.

[a]**Excludes** observations for patients for whom six-week interview data were not collected.

[b]**Includes** observations on patients for whom six-week interview data were not collected.

We did not choose the alternative course of limiting the sample using each applicable guideline as the unit of analysis for weeks one through six to the 240 observations on which we had six-week interview data, since the sample sizes are smaller and thus yield less statistical power to detect differences in adverse outcomes among patients whose care met or did not meet the guidelines.

In addition, the rules that we used to eliminate the double-counting of adverse outcomes when the same unique event (e.g., a fall) would have been treated as an adverse outcome for more than one guideline may lead to an overstatement of the relationship between inadequate care and adverse outcomes.   In the 28 cases in which the same unique event was an outcome for two guidelines, we randomly selected the guideline to be eliminated, except in six cases for which one guideline had been met and the other had not. Because a failure to meet the guidelines increases the likelihood of adverse outcomes, we selected the guideline that was not met in these six cases. Doing so may lead to a slight overstatement of the relationship between inadequate care and adverse outcomes.   However, it should be noted that the random selection of the guideline to be eliminated may have led to an understatement of this relationship.   (For a further discussion on this issue, see Appendix B.)

2.   Less Aggregate Analyses

This analysis of the likelihood of adverse outcomes is quite aggregated. Our ability to conduct less aggregate analysis was severely constrained by the size of the subgroups in the pilot study data.   This is true for subgroups involving subsets of related guidelines, particular types of care

specifications, and particular types of adverse outcomes. With respect to subsets of related guidelines, we had less than 50 observations on the guidelines involving physical therapy, the largest of the subsets of related guidelines that we had hoped to be able to analyze. With respect to care specifications, the great majority of the observations in which care did not meet the guidelines involved the specified number of professional visits. Too few observations were available on other types of specifications to have conducted separate analyses for them.[3] With respect to outcomes, a substantial majority of the observed adverse outcomes involved morbidities. We observed too few health service use outcomes to conduct separate analysis for them. Our ability to conduct subanalyses was particularly constrained by the limited variance in the dependent variable--the presence of adverse outcomes. Even when all types of adverse outcomes and the full six-week follow-up time period were included, only 82 observations (of the total of 741 observations on guidelines) showed adverse outcomes. Moreover, most of the observations on adverse outcomes were concentrated during weeks one through two: only 21 observations with adverse outcomes appeared during weeks three through six, compared with 65 during weeks one through two.[4] Due to these constraints, the subgroup analyses presented **herein** were limited to general types of care (that is, semi/unskilled care and skilled care). All analyses included all types

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[3]**Subanalyses** involving specifications for different types of care were also problematic because we could not link adverse outcomes to the failure to meet particular types of specifications. Specifically, the guidelines do not attempt to distinguish between adverse outcomes associated with the failure to meet the specifications on the number of professional visits and those associated with the failure to meet the specifications on the timing of initial visit.

[4]**Four** observations showed adverse outcomes during weeks one through two **and** weeks three through six.

of care specifications and all types of adverse outcomes.   Most of the
analyses combined the two follow-up periods.

C.   MODEL AND ESTIMATION TECHNIQUE

As noted earlier, we expect that, if the guidelines are valid, adverse
outcomes will be observed substantially more often when care did not meet the
guidelines than when it did.   Thus, to test their validity, we used a **probit**
model to compare the probability of adverse outcomes when care met the
guidelines and when it did not (see, for example, **Tobin,** 1958).   The estimated
model takes the following form:

(1) y = a + **bS** +**cX** t e,

   where :

    AO = O if $y \leq 0$

    AO = 1 if $y > 0$

    AO equals 1 if an adverse outcome was observed, and 0
    otherwise

    S   equals 1 if care failed to meet   the   guideline
    specifications, and 0 otherwise

    X   is   a   set   of   control   variables   measuring patient
    characteristics at discharge

    a, b, and c are the coefficients that were estimated[5]

    y is an unobserved, continuous variable

    e is a random error term.

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[5]**c** is a vector of coefficients.

Table III.8 lists the control variables (and their means) that measure patient characteristics at discharge, using each applicable guideline as the unit of analysis and the sample of 741 cases for analysis of the Basic Guidelines.

The probit model yields an estimate of the probability that the dependent variable (AO, in this case) equals 1 and identifies the factors that are statistically significant for determining the value of that probability. In this case, we are interested in the statistical significance of the coefficient b, the effect of experiencing care that does not meet the guidelines on the probability of adverse outcomes. The derivative of the estimated probability of adverse outcomes with respect to the independent variable on the failure to meet the guideline specifications (S) evaluated at the means of the control variables (X) yields estimates of the probability of adverse outcomes when care meets and does not meet the guidelines, controlling for patient characteristics at discharge.

Because the unit of analysis is each applicable guideline, we frequently have multiple observations for the same patient. Such multiple observations might not be fully independent. In particular, a patient who suffers an adverse outcome according to one guideline may be' more likely to suffer an adverse outcome according to another guideline. This situation could occur due to the existence of patient characteristics (not controlled for in our model) which make the patient vulnerable to adverse outcomes. Non-independence is an important issue because it leads to biased standard errors and t-statistics. (The estimates of the coefficients are not biased.)

However, we found no evidence of non-independence among the observations which showed unique adverse outcomes. The number of cases in which the same

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TABLE III.8

CONTROL VARIABLES AND THEIR
MEANS UNDER THE BASIC GUIDELINES

Variable	Mean
Impairment in Typical Week[a] Prior to Hospitalization	
Impaired in meal preparation	45.7%
Impaired in taking medicines	48.1%
Impaired in bathing	48.4%
Impaired in dressing	41.0%
Impaired in ambulation	37.5%
Impaired in toileting	33.0%
Impaired in transfer	36.4%
Impaired in eating	13.7%
Impairment at Discharge[a]	
Impaired in meal preparation	73.8%
Impaired in taking medicines	78.1%
Impaired in bathing	51.7%
Impaired in dressing	69.9%
Impaired in ambulation	54.4%
Impaired in toileting	45.5%
Impaired in transfer	45.5%
Impaired in eating	21.4%
Severe cognitive or emotional impairment	11.9%
Severity of Illness	
Has Stage III **illness[b]**	**22.9%**
Has significant co-morbidities and Stage II **illness[c]**	47.5%
Multiple hospitalizations in previous six months	15.3%
Prior Community Service Use	
Home health nurse	10.1%
Home health aide	10.3%

TABLE III.8 (continued)

Variable	Mean
Sociodemographic Variables	
Age (in years)	75.4
Female	57.6%
Membership in a minority racial or ethnic group	6.3%
Level of schooling completed[d]	2.9

[a]These variables are scored as 1 if the patient requires human assistance for the task, and zero otherwise.

[b]Automated Disease Staging algorithm. Stage III is defined as: multiple site involvement or generalized systemic involvement and poor prognosis.

'Automated Disease Staging algorithm. Stage II is defined as: problems limited to an organ or system and a significantly increased risk of complications.

[d]No schooling = 1; elementary schooling = 2; high school = 3; college = 4.

patient suffered two or more unique adverse outcomes is quite similar to what one would expect if the observations were fully independent. For weeks one through two, we observed a total of 9 patients who suffered adverse outcomes along unique adverse outcome measures, and we estimate that we would observe 12 such patients if the observations were independent. The proportion of cases with multiple observations of unique adverse outcomes **(9/741)** does not differ to a statistically significant extent from the proportion of such cases expected under independence **(12/741).** The results for weeks three through six are similar. We observed three cases, and would expect to observe two with independent observations. (See Appendix B for a discussion on the procedures used to estimate the number of cases with multiple observations under independence.)

Although there are relatively few cases in which the same patient suffered two or more unique adverse outcomes, there are 28 cases in which an identical outcome event was treated as an adverse outcome for more than one guideline for the same patient, due to the fact that some adverse outcomes applied to more than one condition. For example, consider a patient for whom the guideline on transfer and the guidelines on mobility therapy for the chairbound were applicable. If this patient suffered a single fall, the adverse outcomes for both of these two guidelines would be set to one. However, the fall actually represents a unique outcome event. To treat it as an adverse outcome for both conditions would be to double-count it. **As** noted earlier, we developed a set **of** rules for eliminating one of the repetitions of an identical outcome, so as to prevent double-counting in such situations. These rules are described in Appendix B.

D.   THE RESULTS OF THE ESTIMATION

In this section, we compare the likelihood of adverse outcomes when care meets the guideline specifications with their likelihood when it does not. We begin the section by presenting the results for the Basic Guidelines. We estimate the impact on the likelihood of adverse outcomes of care that does not meet the guidelines, controlling for patient characteristics. The section then describes several **variants** of the guidelines which were developed to test the sensitivity of the estimates of the impact of care that did not meet the guidelines using different specifications of minimally adequate care. We then present estimates of the impact of care that did not meet the guidelines under variants of the guidelines. We conclude the section by presenting the results for different time periods and patients at different risk levels under the Basic Guideline and the most promising variant.

1.   The Results for the Basic Guidelines

Table III.9 presents estimates of the impact of care that did not meet the specifications of the Basic Guidelines on the likelihood of adverse outcomes. These estimates were obtained from the **probit** model described in **Section III.C.** For all care, we estimate that the likelihood of an adverse outcome when care does **not** meet the specifications of the associated guideline is about twice the likelihood of an adverse outcome when care meets the specifications for that guideline. Further, the effect is statistically significant. For skilled care, we estimate that the likelihood of an adverse outcome when care does not meet the guidelines is only about 20 percent greater than the likelihood when care meets the guidelines, and the estimated effect is not statistically significant. For semi/unskilled care, we estimate

TABLE III.9

ESTINATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
BASIC GUIDELINES

	Likelihood of Adverse Outcomes when Care:		Effect of Not Meeting Guidelines:			Size of Sample in which Care:	
Type of Guideline	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - Al	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0398	.1061	.0663	1.237	2.66	347	21
Skilled Care	.0765	.0908	.0163	0.573	1.22	218	155
All Care	.0691	.1322	.0632**	2.189	1.91	565	176

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

*Statistically different fran zero at the 10 percent significance level, using a one-tailed test.
**Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

that adverse outcomes are between two and three times as likely when care does not meet the guidelines as when it does. However, the estimated effects are not statistically significant. The lack of statistical significance may be due to the very small sample of cases in which care did not meet the guidelines for semi/unskilled care.

   Correcting Measurement Problems. In addition to analyses using each applicable guideline as the unit of analysis, we performed some preliminary analysis using the patient as the unit of analysis. (The results from these analyses are presented in Appendix **B.)** The estimates obtained for all care using the patient as the unit of analysis are similar to those obtained using each applicable guideline as the unit of analysis. However, the estimates for skilled care and semi/unskilled care are very different under the two units of analysis. Because cross-overs offered a possible explanation for the difference in the estimates under the two units of analysis, we reviewed the data to investigate the incidence of such cases. (See Section **III.B** above for a discussion of cross-overs.)

   Our review indicated that cross-overs were a particular problem for the semi/unskilled guideline on toileting and for the skilled guideline on pain **management.**[6] Together, these two guidelines accounted for over **50** percent of the adverse outcomes that we observed.

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[6]**We** also discovered one other type of problem pertaining to inconsistencies across outcomes for related guidelines--outcomes that had been included in one guideline, but excluded from a related one. For example, falling, skin breakdown, and new decubiti had been included as outcomes for help with walking but not for mobility therapy for impaired ambulation. Because this was clearly an oversight, we reviewed the guidelines and added outcomes to particular guidelines as appropriate to resolve such inconsistencies. The results for the Basic Guidelines described in this chapter reflect these changes.

Several patients who suffered an adverse outcome for the guideline on toileting experienced care that did not meet the specifications of another guideline, but met those for the Toileting Guideline. Our review of the guideline on toileting indicated that the link between adequate care and adverse outcomes was poorly specified for this guideline. As written, the specifications for care on the Toileting Guideline could be failed only if the patient experienced accidents with his or her bladder or bowels. However, the adverse outcomes associated with toileting included a fall, impaction, and urinary tract infection--outcomes that are unrelated to accident8 with the bladder or bowels. In addition, the number of **observations** in which impaction was reported suggested that some respondents might have confused constipation with impaction.

Similarly, several cross-over cases involved patient8 who suffered an adverse outcome on the Pain Management Guideline and experienced care that met the specifications of that guideline but did not meet the specifications of another guideline. The outcome suffered in all of these cases was pain that interfered with sleep or everyday activities. A further investigation indicated that such pain was reported by over 30 percent of the entire analysis sample.

The extent of report8 of such pain **suggested** that the measure of pain used in our study was problematic. To limit the burden of completing the follow-up interviews, we had relied on a very simple measure of pain. This measure was a report (by the patient or a proxy) of whether' the patient was experiencing pain which interfered with sleep or everyday activities. We had hoped that this approach would allow us to focus on severe pain. However, the

number of reports of pain which interfered with sleep or everyday activities suggested that this approach captured not only severe pain but also minimal pain and discomfort. Fortunately, we had also included a measure of the use of health services associated with pain--specifically, whether the patient had an unexpected visit to a doctor or emergency room or had an unscheduled readmission to a hospital because he or she could not adequately control pain or had taken a pain medication overdose. The use of health services in response to pain is probably a better measure of severe pain than are the reports of pain which interfered with sleep or everyday activities.

We corrected these measurement problems by deleting falling, impaction, and urinary tract infections as outcome measures for the Toileting Guideline. We also deleted pain which interfered with sleep or everyday activities for the guidelines for which it occurred, relying only on the use of health services in response to pain as our measure of pain as an **outcome.**[7]

Table 111.10 presents the results for the **probit** analysis of the Basic Guidelines when these measurement problems were corrected. The estimate of the effect of experiencing care that did not meet the guidelines is larger when these measurement problems were corrected. (Compare Tables III. 9 and 111.10.) The difference is particularly pronounced for the skilled care guidelines; We estimated a 22 percent increase in the likelihood of an adverse outcome before the measurement problems were corrected, and a 106 percent increase after the measurement problems were corrected. The effect

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'Pain which interferes with sleep or everyday activities is an outcome measure under the Basic Guidelines for three types of care: amputation care and preprosthetic training, intravenous therapy for pain medication, and pain management.

TABLE 111.10

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES: BASIC GUIDELINES, CORRECTED FOR MEASUREMENT PROBLEMS

Type of Guideline	Likelihood of Adverse Outcomes when Care: Met Guidelines (A)	Did Not Meet Guidelines (B)	Effect of Not Meeting Guidelines Difference (C = B - A)	t- Statistic	Ratio B/A	Size of Sample in which Care: Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0204	.0922	.0718*	1.412	4.52	347	21
Skilled Care	.0412	.0850	.0438**	1.800	2.06	218	155
All Care	.0436	.1270	.0834***	3.014	2.91	565	176

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

*Statistically different from zero at the 10 percent significance level, using a one-tailed test.
**Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

of experiencing care that did not meet the guideline specifications is statistically significant for semi/unskilled care (at the 10 percent level) and for skilled care, as well as for all care. Before the measurement problem was corrected, we observed a statistically significant effect only for all care.

2. Variants of the Guidelines

Four variants of the guidelines were developed a priori to test how the guidelines performed under different sets of specifications for minimally adequate care. Three of these variants involved changes in the specifications for minimally adequate care under the guidelines, and one involved the treatment of follow-up physician visits in meeting the specifications for minimally adequate care.

a. Description of the Variants

The following four variants were developed a priori:

o Physician Visit Variant

o Problematic Variant

o Uniformly Relaxed Variant

o Uniformly Tightened Variant'

The Uniformly Relaxed and Uniformly Tightened Variant involve arbitrary relaxation and tightening of the specifications of the guidelines. The

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[8]This variant was labeled the Stringent Variant in the Analysis Plan (Phillips, 1988).

Physician Visit and Problematic variant involve selective revisions, the general effect of which is to relax guideline requirements.

Physician Visit Variant. The specifications for care under the Physician Visit Variant are identical to the specifications for the Basic Guidelines, with the exception that visits to a physician for follow-up care are counted toward meeting the specifications for minimally adequate care for many more of the guidelines. Most of the Basic Guidelines assume that physicians do not typically provide the care covered by the guideline: thus, follow-up visits to a physician are not counted toward determining whether the specified number of professional visits were **received.**[9] The Physician Visit Variant counts follow-up physician visits toward meeting the specification on the number of professional visits if it seems reasonable that a physician <u>might</u> provide the care called for in the guideline. Eight of the skilled care guidelines were affected by this change. Table III.11 compares the guidelines for which physician visits are counted under the Physician Visit Variant and Basic Guidelines.

Problematic Variant. The Problematic Variant focuses on the guidelines for which the clinical panel had the most difficulty in setting specifications for minimally adequate care. Two members of the project staff developed the specifications for this variant after reviewing the deliberations of the clinical panel. In keeping with the necessity of defining <u>minimally </u>adequate care, this variant generally specifies more relaxed standards of care for the guidelines with which the panel had difficulty. In addition, some guideline

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'Because data on the timing of the initial follow-up physician **visit** were not collected, we could not count physician visits toward specifications for the timing of the initial visit.

TABLE III.11

TREATMENT OF FOLLOW-UP PHYSICIAN VISITS UNDER THE
PHYSICIAN VISIT VARIANT AND BASIC GUIDELINES

		Counted Under:	
Number	Type of Care	Basic Guidelines	Physician Visit Variant
10A-10C	Diabetic Care	No	Yes
11A-11B	Amputation Care and Preprosthetic Training	No	**Yes**
12A-12B	Eye Care	No	**Yes**
13A-13B	Chest Physical Therapy	No	No
14	Oxygen Therapy	**No**	No
15A-15B	Aerosol Therapy	No	Yes for 15B No for **15A**
16	**Tracheostomy** Care	No	Yes
17	Monitoring Cardiopulmonary Status	Yes	Yes
18	Venipuncture for Blood Drawing	No	No
19	Draw Blood for **Protime**	Yes	**Yes**
20A-20B	Medication Supervision	Yes	Yes
21A-22	IV Therapy via Peripheral Line	No	No
23	IV Therapy via Central Venous Line	No	No
24	**Enteral Feeding/Nasogastric** Tube	**No**	No
25	**Enteral Feeding/Gastrostomy** or Jejunostomy	No	**No**
26	Care for Dysphagia	No	No
27A	Urinary Incontinence Management	No	No

TABLE III.11 (continued)

Number	Type of Care	Counted Under: Basic Guidelines	Physician Visit Variant
27B	Intermittent Catheterization	No	Yes
28A-30B	Care of Urinary Catheter	No	**Yes**
31	Bowel Incontinence Management	No	No
32	Ostomy Care	No	No
33A-33N	Wound Care	No	**Yes**
34	Care of **Bedbound** Patients	No	No
35A-35B	Care of Comatose Patients	No	No
36A-36B	Mobility Therapy for the Chairbound	No	No
37	Mobility Therapy for Impaired Ambulation	No	No
38	Muscle Strengthening Following **Knee** Surgery	No	No
39	Muscle Strengthening Following Hip Surgery	No	No
40	Muscle Strengthening Following Fracture or Paralysis	No	No
41A-41B	Pain Management	**Yes**	**Yes**
42	Cast Care	**Yes**	Yes
43	Psychiatric Monitoring	**Yes**	**Yes**
44	Follow-up of Cognitively Impaired	No	No
45A-45B	Follow-up of Professional Monitoring	**Yes**	Yes

conditions were subdivided further to permit different specifications of minimally adequate care for additional subgroups of patients. Table III.12 defines the standards of care for each guideline under the Problematic Variant. Sixteen guidelines were affected.

Uniformly Relaxed Variant. The Uniformly Relaxed Variant and the Uniformly Tightened Variant (described below) were developed to assess the validity of the Basic Guidelines relative to extreme changes in the specifications for minimally adequate care. Under the Uniformly Relaxed Variant, the specified number of professional visits and the specified timing of the initial professional visit are relaxed uniformly to require one fewer visit and an initial visit made one period later.[10] Conditions which have one professional visit specified under the Basic Guidelines are deleted under this variant.

Uniformly Tightened Variant. Under this variant, the specifications for the number of professional visits and for the timing of the initial professional visit are tightened uniformly to require one more visit and an initial visit made one period earlier (with the exception that the specifications which call for an initial visit the day after discharge are retained). We did not have data on whether an initial professional visit was made on the same day as discharge, and thus could not determine whether such a specification was met.

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[10] The guidelines specify the timing of the initial visit as no later than the day after discharge, the third day after discharge, the fifth day after discharge, or the end of the first week after discharge. For example, if the current specification on timeliness was the day after discharge, we relaxed it to the third day after discharge. It should be noted that an initial visit during the first two weeks is equivalent to having one professional visit. In this circumstance, the two types of specifications are equivalent.

TABLE III.12

REVISED GUIDELINE SPECIFICATIONS UNDER THE
PROBLEMATIC VARIANT

Number	Type of Care	Revision
1-9	Help with Summoning Assistance, Eating, Bed/Chair Transfer, Dressing, Medicines, Walking, Bathing, Toileting, Meal Preparation	None
10A-10C	Diabetic Care	Under variant, 10C applies only if patient has hyperosmolar coma or blood sugar over 500.
11A-11B	Amputation Care and Preprosthetic Training	None
12A-12B	Eye Care	12B is deleted under variant
13A-13B	Chest Physical Therapy	None
14	Oxygen Therapy	None
15	Aerosol Therapy	None
16	Tracheostomy Care	Under variant, specified number of professional visits is two if patient is not impaired in transfer or eating.
17	Monitoring Cardiopulmonary Status	None
18	Venipuncture for Blood Drawing	None
19	Draw Blood for Protime	None
20A-20B	Medication Supervision	Under variant, must have ten medications rather than five for 20B to apply.

TABLE 111.12 (continued)

Number	Type of Care	Revision
21A-22	IV Therapy via Peripheral Line	None
23	IV Therapy via Central Venous Line	None
24	Enteral Feeding/Nasogastric Tube	None
25	Enteral Feeding/Gastrostomy or Jejunostomy	None
26	Care of Dysphagia	Under variant, specification for professional visits is revised to one visit, and timing of initial visit is revised to by third day.
27A	Urinary Incontinence Management	None
27B	Intermittent Catheterization	None
28A-30B	Care of Urinary Catheter	None
31	Bowel Incontinence	Under variant, specification management for professional visits is revised to one visit, and timing of initial visit is revised to by fifth day.
32	Ostomy Care	None
33A-33N	Wound Care	Under variant, specification for professional visits are revised to call for one less visit, and specification on timing of initial visits are revised to call for one period later, except that 33A is unchanged.

TABLE III.12 (continued)

Number	Type of Care	Revision
34	Care of **Bedbound** Patients	Under variant, specification for professional visits is revised to two visits, and timing of initial visit is revised to by fifth day.
35	Care of Comatose Patients	None
36A-36B	Mobility Therapy for the Chairbound	Under variant, specification for professional visit for 36A is revised to two visits, and timing of initial visit is revised to by fifth day. **36B** is deleted.
37	Mobility Therapy for Impaired Ambulation	Under variant, specification for professional visit is revised to two visits, and timing of initial visit is revised to by fifth day.
38	Muscle Strengthening/ Following Knee Surgery	Under variant, specification for professional visits is revised to three visits, and timing of initial visit is revised to by fifth day.
39	Muscle Strengthening/ Following Hip Surgery	Under variant, specification for professional visits is revised to one visit, and timing of initial visit is revised to within first week.
40	Muscle Strengthening/ Fractures and Paralysis	Under variant, specification for professional visits is revised to one visit, and timing of initial visit is revised to within two weeks.

TABLE III.12 (continued)

Number	Type of Care	Revision
41A-41B	Pain Management	None
42	Cast Care	Deleted
43	Psychiatric Monitoring	Deleted
44	Follow-up of the Cognitively Impaired	Deleted
45A-B	Follow-up Professional Monitoring	None

<u>**Specifications**</u> <u>Not Affected **by** Variants</u>. Basic Guideline specifications that are unaffected under a particular variant are retained in that variant. For example, none of the variants involved revising the semi/unskilled guidelines.   Thus, these guidelines were retained as unchanged in the analysis of all care under the variants.   (The correction of the measurement problems under the Basic Guidelines did affect the semi/unskilled guidelines.) In addition, a number of skilled guidelines show specifications for care that do not involve professional visits (e.g., insulin injections for an **insulin-**dependent diabetic): these are retained under all variants.

<u>The Effects of the Variants on the Analysis **Sample**</u>.   Table III. 13 presents information on the sample of observations for which care met and did not meet guidelines under each variant and the Basic Guidelines.   The total sample sizes decline under the Problematic Variant and Uniformly Relaxed Variant because observations on guidelines for which the specifications no longer applied were deleted under these two variants. A major reason for the reduction in sample size is that the specifications of the guideline on medication supervision **were** revised whereby it was applicable to far fewer patients.   (It should be recalled that about one-third of all observations involve this guideline.)   In addition, guidelines that call for one professional visit during the two weeks after discharge were not applicable when specifications on the number of professional visits were relaxed (to "zero visits").   In addition, the total sample sizes under the other variants change slightly due to missing data.   For example, if data were missing on physician visits but not on nursing or therapy visits, we might have been able to determine whether care met the Basic Guidelines but would have been unable

TABLE III.13

SAMPLE SIZES BY VARIANT FOR ANALYSIS OF ADVERSE OUTCOMES WHEN
CARE MET AND DID NOT MEET THE GUIDELINES

| | Number of Observations for Which: | | |
Variant	Care Met the Guidelines	Care Did Not Meet the Guidelines	Total
Basic Guidelines	**565**	176	741
Physician Visit Variant	**584**	**155**	739
Problematic Variant	**485**	142	627
Uniformly Relaxed Variant	459	91	550
Uniformly Tightened Variant	**485**	**256**	741

NOTE: The unit of analysis is each applicable guideline. Cases missing data
on whether care met the guidelines or on adverse outcomes are excluded.

to determine whether it met the Physician Visit Variant. Because the specifications for care changed under the variants, the number of observations for which care did not meet the specifications also changed under the variants. The changes are dramatic for the Uniformly Relaxed and Uniformly Tightened Variants and moderate for the Physician Visit and Problematic Variants.

b.   <u>Results for the Variants.</u> We consider first the results for the variant most similar to the Basic Guidelines--the Physician Visit Variant, which retains the specifications of the Basic Guidelines. We then consider the three variants which involved revisions to the specifications: the Problematic, Uniformly Relaxed, and Uniformly Tightened Variants.

<u>Physician Visit Variant.</u>   Table III.14 presents the results for the Physician Visit Variant. The effect for skilled care is somewhat larger under the Physician Visit Variant than under the Basic Guidelines, although it is not statistically significant in either case.   (Compare Tables III.9 and 111.14.) The effect of care that does not meet the skilled care guidelines under the Physician Visit Variant is equivalent to a 36 percent increase in **the likelihood** of adverse outcomes, compared with a 22 percent increase under the Basic Guidelines. **Due** to the increase in the effect for skilled care, the effect for all care also increases.   (It should be recalled that the semi/unskilled guidelines are unchanged under the Physician Visit Variant.)

Because our results improved when we corrected measurement problems and under the Physician Visit Variant, we combined them.   Table III.15 presents the estimated effect on adverse outcomes of experiencing care that does not meet the guidelines under this combination.   The estimated effect for skilled

TABLE III.14

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATEO GUIDELINES: PHYSICIAN VISIT VARIANT

Type of Guideline	Likelihood of Adverse Outcomes when Care:		Effect of Not Meeting Guidelines			Size of Sample in which Care:	
	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A)	t-Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0398	.1061	.0663	1.237	2.66	347	21
Skilled Care	.0726	.0989	.0262	0.830	1.36	237	134
All Care	.0694	.1416	.0722**	2.276	2.04	664	155

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

  *Statistically different from zero at the 10 percent significance level, using a one-tailed test.
 **Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

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TABLE III.15

**ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
PHYSICIAN VISIT VARIANT, CORRECTED FOR MEASUREMENT PROBLEMS**

Type of Guideline	Likelihood of Adverse Outcomes when Care:		Effect of Not Meeting Guidelines			Size of Sample in which Care:	
	Net Guidelines	Did Not Meet Guidelines (B)	Difference (C = B - A)	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0204	.0922	.0718*	1.412	4.52	347	21
Skilled Care	.0401	.0972	.0571**	1.994	2.42	238	134
All Care	.0430	.1439	.1009***	3.200	3.35	585	155

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines
were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge.   The sample includes
observations on guidelines for patients on whom six-week interview data were not collected.   Such patients are assumed to have suffered no
adverse outcomes during weeks three through six.

 *Statistically different from zero at the 10 percent significance level, using a one-tailed test.
 **Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

care in this combination is larger than when the measurement problems were corrected under the Basic Guidelines. (Compare Tables 111.10 and 111.15.) If the goal is to maximize the estimates of the effect on the likelihood of adverse outcomes of care that does not meet the guidelines, this combined variant is the optimal specification of our model.

Variants Involving Changes in Standards. Tables 111.16, 111.17, and III.18 present the results for the Uniformly Tightened, Problematic, and Uniformly Relaxed Variants, respectively. The comparable results for the Basic Guidelines were presented in Table 111.9. As with the Basic Guidelines, these variants retain the outcome measures on toileting and pain from the Basic Guidelines. Under each of the three variants involving changes in standards of care, we estimated negative effects for skilled care: that is, we estimated that adverse outcomes are less iikely when care does not meet the guidelines than when it does.

Consider the estimate for skilled care for the Uniformly Tightened Variant. The overall sample for the analysis of this variant is the same as that of the Basic Guidelines. However, the number of cases in which care did not meet the guidelines is substantially greater (see Table 111.13). Although the 'estimates for this variant are not statistically significant, the negative sign suggests that the Uniformly Tightened Variant does not provide a better specification of minimally adequate care.

The signs of estimates for the Problematic and Uniformly Relaxed are also negative. In addition, they are statistically significant. While the number of observations in which care did not meet the guidelines is smaller under these variants than under the Basic Guideline, the overall sample sizes are

TABLE 111.16

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
UNIFORMLY TIGHTENED VARIANT

Type of Guideline	Likelihood of Adverse Outcomes when Care:		Effect of Not Meeting Guidelines			Size of Sample in which Care:	
	Net Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = 8 - A)	t-Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0398	.1061	.0663	1.237	2.66	347	21
Skilled Care `	.0855	.0784	-.0070	-0.246	-0.92	138	235
All Care	.0690	.1138	.0448**	1.839	1.65	485	256

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

*Statistically different from zero at the 10 percent significance level, using a one-tailed test.
**Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

TABLE III.17

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES: PROBLEMATIC VARIANT

Type of Guideline	Likelihood of Adverse Outcomes when Care:		Effect of Not Meeting Guidelines			Size of Sample in which Care:	
	Met Guidelines	Did Not Beet Guidelines (B)	Difference (C = B - Al	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0398	.1061	.0663	1.237	2.66	347	21
Skilled Care	.1240	.0550	-.0690**	-1.841	-0.44	138	121
All Care	.0852	.1280	.0429*	1.291	1.50	485	142

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge.   The sample includes observations on guidelines for patients on whom six-week interview data were not collected.   Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

 *Statistically different from zero at the 10 percent significance level, using a one-tailed test.
 **Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

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TABLE III.18

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
UNIFORMLY RELAXED VARIANT

| Type of Guideline | Likelihood of Adverse Outcomes when Care: | | Effect of Not Meeting Guidelines | | | Size of Sample in which Care: | |
	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A)	t-Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	.0398	.1061	.0663	1.237	2.66	347	21
Skilled Care	.1695	.0501	-.1194**	-2.521	-0.30	112	70
All Care	.0946	.1510	.0564*	1.338	1.60	459	91

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

*Statistically different from zero at the 10 percent significance level, using a one-tailed test.
**Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

also smaller. The changes in overall sample sizes are sensitive to changes in one guideline, the Medication Supervision Guideline. As discussed in Section **III.A,** this guideline accounts for 147 of all observations under the Basic Guidelines. Under the Problematic Variant, the specifications no longer applied for 110 observations on the Medication Supervision Guideline, and these observations were deleted. Deleting observations on the Medication Supervision Guideline under the Uniformly Relaxed Variant had a **major** impact on the sample size for the analysis of that variant. We also corrected the measurement problems on pain and the Toileting Guideline for the Problematic Variant. The estimated effect is still negative under the combination. However, the magnitude of the negative effect was considerably smaller than under the Problematic Variant **before** the measurement problem was corrected, and the effect was no longer statistically significant.

In summary, when we tighten **or** relax the standards of the Basic Guidelines, we obtain estimates that indicate that adverse outcomes are <u>less</u> likely when care does not meet the guidelines than when it does. These estimates are less reasonable than those of the Basic Guidelines. These results are encouraging, because they suggest that the standards for the Basic Guidelines are neither too relaxed nor too tight. However, the fact that much of the difference between the samples for the Basic Guidelines and for the Problematic and Uniformly Relaxed Variants is associated with changes in the Medication Supervision Guideline reinforces our concern about the prominence of observations on this guideline. If changes in the Medication Supervision Guideline are contemplated, the effect of these changes on this analysis, and thus on the evidence of the validity of the guidelines a<u>s a **group,**</u> should be investigated.

3.　Results for Different Time Periods

To this point in our analyses, we have focused on outcomes during the full six-week period following discharge. However, the data on outcomes *were* collected for two time periods--for the first two weeks immediately following discharge and for weeks three to six following discharge. An examination of the pattern of results for these two time periods may be useful for establishing an optimal follow-up period for a national study.

Tables III.19 and 111.20 present the results on the effect of care that did not meet the guidelines under the Basic Guidelines and under the Physician Visit Variant with the measurement problems corrected (the optimal specification of our model) on the likelihood of adverse outcomes. The results in both tables indicate that most adverse outcomes were suffered in the immediate post-discharge period, regardless of whether or not care met the guidelines. For example, *we* estimate that about ten percent of the observations for which care did not meet the Basic Guidelines (Table 111.19) involved adverse outcomes in weeks one through two, compared with about 2 percent in weeks three through six.

Almost all of the outcomes during weeks three through six involved unexpected service use. As described in Chapter II, morbidities which might be a delayed consequence of inadequate care during weeks one through two were measured during weeks three through six. There are only two such morbidities--contractures and decubiti. In addition, depression was measured at six weeks. The effect on adverse outcomes of care that did not meet the guidelines in weeks one through two is large and statistically significant in both models. The effect in weeks three to six is not statistically

TABLE III.19

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES FOR DIFFERENT TIME PERIODS WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
ALL CARE UNDER THE BASIC GUIDELINES

| Type of Guideline | Likelihood of Adverse Outcomes when Care: | | Effect of Not Meeting Guidelines | | | Size of Sample in which Care: | |
	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A)	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Weeks One through Two	.0514	.1030	.0517**	2.035	2.00	571	176
Weeks Three through Six	.0089	.0199	.0110	1.089	2.24	531	147
Weeks One through Six	.0691	.1322	.0632**	2.189	1.91	565	176

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge.   The sample includes observations on guidelines for patients on whom six-week interview data were not collected.   Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

  *Statistically different from zero at the 10 percent significance level, using a one-tailed test.
 **Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different fran zero at the 1 percent significance level, using a one-tailed test.

TABLE III. 20

ESTIMATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES FOR DIFFERENT TIME PERIODS WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES:
PHYSICIAN VISIT VARIANT, CORRECTED FDR MEASUREMENT PROBLEMS

Type of Guideline	Likelihood of Adverse Outcomes when Care:,		Effect of Not Meeting Guidelines			Size of Sample in which Care:	
	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A]	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
Weeks One through Two	.0207	.1150	.0943***	3. 370	5. 55	585	161
Weeks Three through Six	.0093	. 0200	.0107	0. 922	2. 15	550	126
Weeks One through Six	.0430	.1439	.1009***	3. 200	3. 35	585	155

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

*Statistically different from zero at the 10 percent significance level, using a one-tailed test.
**Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

significant in either model; however, the effect of experiencing care that did not meet the guidelines still represents a large percentage increase. Regardless of which model we used, we estimate that the likelihood of an adverse outcome in weeks three through six is twice as great when care does not meet the guidelines as when it does. These results indicate that, while only a minority of adverse outcomes extend beyond the immediate post-discharge period, those that do occur tend to be serious enough to involve unexpected health service use. This finding suggests that a follow-up period longer than two weeks is desirable.

4. The Results for Patients at High Risk and Not at Hinh Risk

As discussed in Chapter II, patients at high risk of experiencing care that did not meet the guidelines and of suffering adverse outcomes were oversampled in the pilot study relative to their proportion in the population. The purpose of oversampling high-risk patients was to obtain a sufficient sample of patients who experienced care that did not meet the guidelines and who suffered adverse outcomes, so as to support a comparison of the incidence of adverse outcomes among patients who had adequate care and those who did not. Slightly less than half (46.8 percent) of the 299 patients in the analysis sample are high-risk patients.

Up to this point in the analysis, we have been treating the observations on all patients as equivalent, regardless of their risk level. This treatment implicitly assumes that the relationship between experiencing care that does not meet the guidelines and of suffering adverse outcomes is comparable across patients of various risk levels. To test this assumption, we estimated selected specifications separately for observations on patients at high risk

and on patients not at high risk under the Basic Guidelines. Table III.21 presents the results for all care and adverse outcomes during weeks one through six. These results indicate that the effect on adverse outcomes of care that does not meet the guidelines is roughly comparable for patients at high risk and not at high risk. Although the effect of care that does not meet the guidelines is not statistically significant for the observations on patients not at high risk, the percentage increase in the likelihood of adverse outcomes is of comparable magnitude for those at high risk (65 percent increase) and those not at high.risk (50 percent increase).

E. SUMMARY AND CONCLUSIONS

The analysis presented in this chapter was based on the assumption that, if the specifications of adequate care embodied in the Basic Guidelines reflect minimally adequate care, we would be substantially more likely to observe adverse outcomes when care does not meet the guidelines than when it does. (It should be recalled that minimum adequacy was defined in terms of care that was minimally adequate to prevent adverse outcomes.)

The results show'that adverse outcomes are more likely when care does not meet the guidelines than when it does under the Basic Guidelines. Controlling for the characteristics of patients and using each applicable guideline as the unit of analysis, we derived estimates whose sign suggests that adverse outcomes are more likely for skilled care, semi-unskilled care, and all care. However, the estimated effect for skilled care is small, and the estimated effect for all care is the only statistically significant estimate.

When we resolved some measurement problems involving an outcome on pain and certain of the outcomes on toileting by dropping the problematic measures

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TABLE III.21

ESTINATES OF THE LIKELIHOOD OF ADVERSE OUTCOMES FOR PATIENTS AT DIFFERENT RISK LEVELS WHEN CARE MET AND DID NOT MEET THE ASSOCIATED GUIDELINES

| Risk Level | Likelihood of Adverse Outcomes when Care: | | Effect of Not Meeting Guidelines | | | Size of Sample in which Care: | |
	Met Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A)	t- Statistic	Ratio B/A	Met Guidelines	Did Not Meet Guidelines
High Risk	.1007	.1657	.0650*	1.516	1.64	354	98
Not at High Risk	.0355	.0533	.0178	0.688	1.50	211	78
All	.0691	.1322	.0632**	2.189	1.91	565	176

NOTE: The unit of analysis is each applicable guideline. Differences among the groups of observations for which care met and did not meet the guidelines were estimated using probit analysis and by controlling for the characteristics of individual patients at discharge. The sample includes observations on guidelines for patients on whom six-week interview data were not collected. Such patients are assumed to have suffered no adverse outcomes during weeks three through six.

  *Statistically different from zero at the 10 percent significance level, using a one-tailed test.
 **Statistically different from zero at the 5 percent significance level, using a one-tailed test.
***Statistically different from zero at the 1 percent significance level, using a one-tailed test.

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(but retaining the specifications of the Basic Guidelines), the estimated effects were larger. We estimate that the effect of care that does not meet the guidelines is to double the likelihood of adverse outcomes for skilled care, to more than quadruple it for semi/unskilled care, and to triple it for all care. Moreover, the estimates are statistically significant (at least at the 10 percent level) for skilled care, semi/unskilled care, and all care.

Counting follow-up physician visits toward meeting the specifications for the number of professional visits for more of the guidelines also yielded a larger estimated effect for skilled care relative to the Basic Guidelines.

All the variants of the guidelines that entailed revisions of the specifications of the Basic Guidelines yielded unreasonable results, performing less well than the Basic Guidelines themselves. For each of these variants, we estimate that adverse outcomes are <u>less</u> likely when care does not meet the guidelines than when it does. However, the results for two of these variants are sensitive to the specification for a single guideline, the Medication Supervision Guideline, which is applicable more frequently than any other guideline.

Overall, the body of the evidence presented herein indicates that, taken as a group, the Basic Guidelines do provide a reasonable specification of minimally adequate care. The effect of experiencing care that does not meet the specifications of the Basic Guidelines is to increase the likelihood of adverse outcomes. Furthermore, when we either tightened **or** relaxed the standards of the Basic Guidelines, we obtained estimates that are less reasonable than those for the Basic Guidelines.

The evidence also suggests possible refinements to the Basic Guidelines-- including follow-up visits to the physician toward meeting the standards of care on the number of professional visits for more of the guidelines, broadening the measure of the adequacy of care for the Toileting Guideline, and changing the measure of pain. In addition, the guideline on medication supervision should be reviewed carefully, and the **appropriateness** of the current specification confirmed or a revised specification adopted. If a revised specification is adopted, the effect of the revision on the validity of the guidelines as a group should be considered.

IV. THE EFFECTIVENESS OF THE SCREENING AND RISK CLASSIFICATION PROCEDURES

It is obviously important that the data collection for a study of the adequacy of post-hospital community care focus specifically on the patients who have a need for such care. In this study, it is also important that patients be characterized by the level of the risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes, so that high-risk patients can be sampled at a higher rate than low-risk patients. This sampling strategy will help ensure that we can obtain (without prohibitive expense) a sufficient sample of patients who experience care that does not meet the guidelines and who suffer adverse outcomes to support an analysis investigation of the relationship between inadequate care and adverse outcomes.

The screening and risk classification procedures used in the pilot study were applied serially. First, the screening procedures were used to identify those who needed care. Then, the risk classification procedures were applied to those who were identified as needing care, and a risk level was assigned to them.

The purpose of the analyses described in this chapter is to assess the effectiveness of the screening and risk classification procedures developed for the pilot study. The analysis consists of two distinct components. First, we consider whether the patients identified as needing care according to the screening procedures also needed care under the guidelines. Second, we consider the effectiveness of the risk classification procedures in identifying patients who actually experienced care that did not meet the guidelines and who suffered adverse outcomes. All of the analyses discussed in this chapter apply to the Basic Guidelines.

A.   NEED FOR CARE

Because the guidelines focus on nursing, therapy, and personal care, our goal in designing the screening procedures and instruments was to identify patients who needed these types of care after their discharge from the hospital.   As in the guidelines, we defined personal care broadly in the screening procedures to include help with meal preparation, help with summoning assistance, [1] and help with the administration of medicines--tasks that are obviously pressing in the immediate post-discharge period.

Our original intent was to exclude two types of patients. The first type to be excluded comprised patients whose only need in the immediate post-discharge period was help with household activities, such as housecleaning.* The rationale for excluding household activities is that these tasks involve minimal care needs that are not critical in the immediate post-discharge period.   The second type of patient to be excluded comprised those whose only need in the immediate post-discharge period was for routine follow-up physician care.[3]   The rationale for excluding these patients rests on the scope of the guidelines.   The screening procedures were designed to identify . patients to whom the guidelines would apply.   While some guidelines covered

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[1]Initially, we did not include help with summoning assistance as part of our broader definition of personal care, because we did not originally envision a guideline on this issue.   The ability to summon assistance in the event of a-emergency was considered in conjunction with such problems as transportation as a barrier to care.   However, later as the guidelines were refined, we developed a guideline for summoning assistance.

[2]However, it should be noted that meal preparation is included under our broad definition of personal care.

[3]Patients who needed help both with household activities and routine follow-up physician visits, but who did not require any other post-hospital care, were also to be excluded.

care that might be provided by a nurse (or nurse practitioner) <u>or</u> a physician, the guidelines were designed to **cover** all common conditions that required nursing, therapy, or personal care in the immediate post-discharge period. Conditions that specifically required follow-up <u>physician</u> care were not considered as the guidelines were being developed. Therefore, the guidelines would be applicable to patients whose conditions required only routine follow-up physician care only if a nurse might also have provided the care.

1.   <u>Procedures for Identifvina Those Who Needed Skilled Care</u>

The procedures for identifying those who needed post-discharge nursing and therapy (skilled care) differ from the procedures for identifying those who needed personal care (semi/unskilled care).   We discuss the procedures for skilled care in this section.   The next section considers the procedures for identifying those who needed semi/unskilled care.

For skilled care, the initial step was to compare the information on conditions (diagnoses) and surgical procedures for each patient with a list of conditions and procedures which typically require skilled care in the immediate post-discharge period and for which we had developed guidelines. TablbIV.l lists these conditions and procedures and their associated ICD-9-CM codes. If the ICD-9-CM codes available at the time of screening or information on conditions and procedures collected in the patient screening interview indicated that the patient suffered from one or more of these conditions or that one of more of these procedures was performed during his /her recent hospital stay,[4] he or she was assumed to have needed skilled care and passed the screen for skilled care.

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[4] We refer here to the hospital stay during which the patient was selected for this study.

TABLE IV.1

CONDITIONS AND PROCEDURES SCREENED IN AS TYPICALLY REQUIRING
POST-HOSPITAL CARE

Care Need	ICD-9-CM Code
Diabetic Care	**250.1X - 250.9X, 251.0X**

Amputation
  Care and
  Preprosthetic Training
	84.00, 84.0, 84.03 - 84.08,
	84.10, 84.12 - 84.17, **84.3X,**
	896.XX - 897.XX

Lens Procedure Care	**13.XX**[a]
Chronic	**490.XX - 496.XX** Chronic **ObstructivePulmonary** Disease **(COPD)**
Tracheostomy Care	30.3x - 30.4X, 31.X, **31.2X**[a]

Monitoring
  Cardiopulmonary
  Status
	401.0X, 402.0X, 403.0X, 404,0X
	405.0X, 410.XX, 411.1X, 428.0X,
	428.1X, 437.2X, **490.XX - 496.XX**
	514.XX

Medication Supervision	**960.XX - 977.XX, E850.XX - E858.9X,** **E930.XX - E949.XX**
IV Therapy via Central Venous Line	**38.93**[a]
Enteral Feeding	43.1x - **43.2X, 46.39**[a]
Dysphagia	787.2X
Care for Urinary Catheter	**55.02**[a]
Ostomy Care	46.1X, **46.2X,** 56.5X - **56.7X**[a]
Wound Care	**84.11**[a]

Muscle Strengthening
  Flexibility and Tone
  Management **(Knee)**
	79.86, 80.06, 80.16, 80.46, 80.66,
	80.76, 80.86, 80.96,
	81.22, 81.41 - **81.47**[a]

TABLE IV.1 (continued)

Care Need	ICD-9-CM Code
Muscle Strengthening Flexibility and Tone Management (Hip)	81.22, 81.5X, **81.6X**[a]
Muscle Strengthening Flexibility and Tone Management (Other)	**342.XX, 810.XX - 819.XX**
Psychiatric Monitoring	295.7X, **296.2X,** 296.3X, 296.5X3, 296.6X, 296.82, **298.0X, E950.XX - E958.XX**
Follow-Up of Cognitively Impaired	**290.0X, 290.1X, 290.4X,** 290.8X - **290.9X,** 294.1X, 294.8X - 294.9X. **331.0X -** 331.2X, 780.55, 783.3X
Follow-Up Professional Monitoring	**32.XX 33.0X,** 33.1X, **33.3X - 33.5X, 34.0X,** 34.1x, 34.3x - 34,9x, **35.XX - 37.XX,** 38.04, 38.05, 38.14 38.15, 38.34, 38.35, 38.44, 38.45 38.64, 38.65
	41.4X, 41.5X, 41.93 - 41.95, **42.0X, 42.1X,** 42.3X - **42.8X, 43.0X,** 43.3X - 43.9X, **44.0X,** 44.2X - **44.9X, 45.0X,** 45.5x - **45.9X, 46.0X,** 46.5X - 46.94, **47.XX, 48.0X,** 48.1X, 48.4X - **48.6X,** 48.9X **, 50.0X,** 50.2X - 50.6X 51.04, 51.2X - 51.9X, **52.0X,** 52.12 - 52.8X, 52.92 - 52.99, 53.7X, 53.8X, 54.1X - **55.0X,** 55.1x, 55.3x - 55.91, 55.97, 55.98, 56.2X, 56.4X, **56.8X, 57.5X,** 57.8X, 60.2X - **60.6X, 65.0X, 65.2X, 65.9X,** 68.3X - **68.8X**[a]

NOTE: The letter **"X"** indicates that any digit is acceptable in that position, including blank.

[a]**ICD-9-CM** codes are procedure codes.

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In the screening procedures to identify patients who needed skilled care, we supplemented the information on conditions and procedures with additional information. We did so because information on conditions and procedures suffers from two major insufficiencies. The first is a function of the timing of data collection in this study. Because the ICD-9-CM codes to be used in screening were not available for every patient at the time of sample intake,[5] we were forced to rely on information reported to us by the patients or their proxies in the patient screening interview. Such self-reports are error-prone. The second insufficiency is a function of the fact that hospital ICD-9-CM codes provided only a portion of the information that was necessary for characterizing a patient's need for post-discharge care. There are a number of conditions and procedures for which only a minority of patients will require skilled care after their discharge.

To supplement information on conditions and procedures, we included a number of other items on skilled care in the screening interviews. They included advanced age, indicators of possible unmet need for skilled care, and the reported receipt of nursing or therapy.'

Table IV.2 lists all of the indicators used to identify patients who needed skilled care and the numbers and percentages of patients to whom these indicators applied among all patients for whom screening was completed and

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'Delaying sample intake long enough to ensure that ICD-9-CM codes were universally available would have delayed the screening and subsequent full two-week interviews which collected information on service receipt and outcomes. For these interviews, a short recall period was critical.

'Services received in the post-discharge period could have been used as an indicator because we conducted the screening interview after the immediate post-discharge period. It should be noted that our purpose was to identify patients for further study, not to predict the need for post-discharge care at the time of discharge.

TABLE IV.2

SCREENING INTERVIEW INDICATORS OF NEED FOR SKILLED CARE

Indicator	Screening Sample		Analysis Sample	
	Number	Percent of Patients	Number	Percent of Patients
Had condition or procedure that typically requires post-hospital care"	655	77.4	233	77.9
Received nursing care or therapy within two weeks after discharge	288	34.0	115	38.5
Advanced age (85 or older)	77	9.1	39	13.0
Referral to or recommendation by physician for formal nursing care or therapy (but did not receive it)	61	7.2	30	10.0
Patient/proxy report of unmet need for nursing care or therapy within two weeks after discharge	16	1.9	9	3.0
Unscheduled hospitalization	32	3.8	14	4.7
Institutionalization within two weeks after discharge	7	0.8	5	1.7
Unscheduled emergency room or urgent care center visit within two weeks after discharge	78	9.2	29	9.7
Death (within two weeks after discharge)	8	0.9	6	2.0
Sample size (patients)	846[a]		299[b]	

NOTE: Multiple indicators may apply to the same patient.

[a] A total of 1,222 indicators are applicable to 846 patients in the screening sample.

[b] A total of 480 indicators are applicable to 299 patients in the analysis sample.

among patients in the analysis sample. The great majority of patients in the analysis sample were selected from among those identified by the screening procedures as needing skilled care. [7] The percentages in the tables do not sum to 100 percent because multiple indicators were applicable to many patients.

The data in Table IV.2 indicate that information on conditions and procedures was very important in identifying those who needed skilled care. Over 75 percent of the patients in both the screening and analysis sample exhibited one or more of the conditions or procedures that typically require post-hospital care. However, the importance of other indicators is also apparent. Information on other indicators was used to screen in the remaining patients identified as needing skilled care.

2. Procedures to Identify Those Who Needed Semi/Unskilled Care

The primary vehicle for identifying patients who needed semi/unskilled care was a series of items in the screening interview that requested information on impairment in personal care activities (following the broad definition of personal care discussed above) and mental or emotional impairment. In general, the definitions of impairment in personal care activities follow the definitions used in the guidelines.[8] However, to

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[7]The analysis sample contains 20 patients who were screened in as needing only semi/unskilled care and 26 patients who were screened in as not needing care. The latter were retained in the analysis sample because a majority of them were determined to need care under the guidelines.

[8]Patients who exhibited the following types of characteristics were treated as impaired and needing assistance under the semi/unskilled guidelines: (1) those who had human assistance in performing an activity; (2) those who did not perform an activity because they could not do so: and (3) those who performed an activity alone, but for whom doing so was very painful or exhausting or took an extremely long time and who lived alone or had no one willing or able to assist them. Due to an error in the code for the screening interview, the third group (that is, those who lived alone, performed an activity alone, and reported that it was painful or exhausting, or that it

minimize the time required to conduct the screen, we combined several of the personal care tasks. Only eating and transfer were considered separately, because information on eating and transfer was necessary for measuring the risk both of experiencing care that did not meet the guidelines and of adverse outcomes.[9] A patient was treated as having a mental or emotional impairment if his or her caregiver reported that the patient required constant supervision due to mental or emotional impairment," or that the patient's ability to perform daily activities was affected nearly every day by mental or emotional problems.

To supplement the information on impairment, we included items in the screening procedures to ascertain the reported receipt of personal care and an indicator of possible unmet need for semi/unskilled care.

Table IV.3 lists the indicators used to identify patients who needed semi/unskilled care and the number and percentages of patients to whom these indicators applied in the screening sample and in the analysis sample, respectively. As with the indicators of skilled care, multiple indicators may have applied to the same patient.

3. Effectiveness of Procedures to Identify Those Who Needed Care

To assess the effectiveness of our screening procedures in correctly identifying care needs, we compared the type of care needed according to these

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took an extremely long time) were not treated as impaired at the time of screening. The other two groups were treated as impaired.

'After fielding had begun, transfer was deleted as a risk indicator.

[10]A reference to mental or emotional problems was added to the question on the need for supervision when it became apparent that some caregivers were responding in terms of supervision due to physical condition, rather than to mental or emotional problems.

TABLE IV.3

SCREENING INTERVIEW INDICATORS OF NEED FOR SEMI/UNSKILLED CARE

	Screening **Sample**		Analysis **Sample**	
	Number	Percent of Patients	Number	Percent of Patients
Impairment in activities of daily living:'				
Eating	86	10.2	64	21.4
Transfer	204	24.2	106	35.5
Other personal care	301	35.7	141	47.2
Medicines	352	41.6	152	50.8
Meal preparation	371	44.0	150	50.2
Impaired cognitive or emotional state at discharge, whereby supervision was required or **patient's daily** activities were affected	116	13.7	78	26.1
Personal **care**[b] assistance within two weeks after discharge (formal or informal)			184	61.5
Patient/proxy report of unmet need for personal **care**[b] within **two** weeks after discharge	75	8.9	39	13.0
Sample size (patients)	**846**[c]		**299**[d]	

NOTE: Multiple indicators may apply to the same patients.

"Defined as having human assistance, performing an activity alone but which was painful or exhausting or took an extremely long time, or not performing an activity and could not have done so.

[b]**Defined** to include help with meal preparation and the administration of medication.

[c]**A** total of 1,505 indicators are applicable to 846 patients in the screening sample.

[d]**A** total of 914 indicators are applicable to 299 patients in the analysis sample.

<u>screening Procedure</u>s with the type of   care needed according to the <u>guidelines</u>.   In this section, we first describe the sample for this analysis and then present the results.

   a . **Sample**

   The sample for the analysis of the effectiveness of the screening procedures is the sample of patients for whom we had information from the **two-**week interview and medical record abstracts--that is, the sample of patients to whom we could apply the guidelines.   The two-week interview and the medical record abstract were completed for 299 patients who met the eligibility criteria for this **study.**[11]   However, due to missing data, there were ten patients for whom we could not determine their need for care based on the guidelines.   (For a discussion of missing data in the application of the guidelines, see Section V.B.)

   In order to test whether or not the screening procedures erroneously excluded patients who needed care according to the guidelines (that is, producing false negative cases), we deliberately included within the analysis sample a small sample of patients identified by the screening procedures as needing no care. [12] The sample of 299 patients contains 24 patients who needed no care according to the screening procedures and for whom we had the

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   [11]**Two** patients on whom these data were collected were determined later to be ineligible.

   [12]**This** sample is small because collecting all the data necessary to have applied the guidelines was very expensive, and observations on patients who according to the guidelines needed no **care were** useful_only for this analysis of screening procedures. Increasing the sample size sufficiently to support precise estimates of the incidence of false negative cases would have been **prohibitively expensive.**

information necessary to apply the **guidelines.**[13] We used the data on these 24 patients to investigate the incidence of false negative cases.

For the remaining 265 patients in the analysis sample, the important issue involved in assessing the effectiveness of the screening procedures is the incidence of cases identified by the screening procedures as needing care but for whom no guideline was applicable--that is, false positive cases.

False negative cases present a much more serious problem for the screening procedures than do false positive cases, since, in a national study, patients identified by the screening procedures as needing no care would be excluded from further study. The exclusion of a non-trivial portion of patients who actually need care could lead to an understatement of the percentage of patients who experience care that does not meet the guidelines and who suffer adverse outcomes. To avoid such understatement, we must develop screening procedures whereby they correctly identify all or almost all patients who need the types of post-discharge care of interest. It is for this reason that we included a comprehensive list of indicators of the need for care in the screening procedures, even though they were often redundant. In contrast, the inclusion of false positive cases **would** not affect estimates of the percentage of the population who experience care that does not meet the guidelines and who suffer adverse outcomes. However, the inclusion of false positive cases would increase data collection costs and should thus be minimized as much as possible.

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[13]A total of 26 patients who were identified in screening as needing no care were included in the analysis sample; however, due to missing data, we were unable to determine whether any guidelines were applicable to two of these patients.

b.   Results

Table IV.4 compares the type of care needed according to the screen with
the type of care needed according to the guidelines for the 289 analysis
sample patients for whom this comparison was possible.[14]   As the table
indicates, there were 15 false negative cases: twelve of these patients needed
skilled care according to the guidelines, and three patients needed only
semi/unskilled care according to the guidelines.   Table IV.4 also indicates
a total of eight false positive cases; five of these patients needed skilled
care according to the guidelines, and three needed only semi/unskilled care
according to the guidelines.

False Negative Cases: Skilled Care.   The percentage of false negative
cases among those screened out is quite high.   The 15 false negative cases
represent 62.5 percent of the 24 cases identified by the screening procedures
as needing no care.   Because the sample consists only of 24 cases, the
confidence interval around the estimate of 62.5 percent is quite large; a 95
percent confidence interval on the percentage of false negative cases among
those screened out as not needing care is 42.7 to 82.3 percent.

To keep the proportion of false negative cases in perspective, it is
important to point out that the 15 false negative cases represent only a small
percentage- (5.5 percent) of all the cases who needed care under the
guidelines.   Because the sample is larger, the confidence interval around this
percentage   is much narrower.   A 95 percent confidence interval   on the

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[14]These results on the incidence of false positive and false negative
cases also apply to the Basic Guidelines corrected for measurement problems.
The correction of the measurement problem does not affect the applicable
conditions.

TABLE IV.4

COMPARISON OF THE INDICATION OF NEED FOR POST-HOSPITAL CARE
FROM THE SCREEN AND THE GUIDELINES

	Indication of Need for Care Based on the Guidelines			
Indication of Need for Care Based on Screen	Skilled	Semi/ Unskilled (only)	None	Total
Skilled	212	28	5[a]	245
Semi/Unskilled (only)	11	6	3[a]	20
None	12[b,c]	3[b]	9	24
Total	235	37	17	289[d]

[a]Cases in this cell are false positives.

[b]Cases in this cell are false negatives.

'Eight of these twelve patients also needed semi/unskilled care according to guidelines.

[d]Due to missing data, we were unable to determine the need for care for 10 sample members based on the guidelines. Two of these needed no care according to the screen.

percentage of false negative cases among those who needed care under the guidelines is **2.8** to **8.2** percent.

Table IV.5 presents the skilled guidelines applicable to the twelve false negative cases for skilled care. Fifteen skilled care guidelines applied to these twelve cases. Table IV.6 presents the semi/unskilled guidelines applicable to all false negative cases, including three false negative cases for which only semi/unskilled guidelines were applicable and five false negative cases for which skilled guidelines were also applicable. Each table also includes the distribution of the true positive cases. In Table IV.5, the true positive cases include those patients identified as needing skilled care according to the screen who were also determined to need skilled care according to the guidelines. In Table IV.6, the true positive cases include those patients identified as needing semi/unskilled care in the screen and determined to need semi/unskilled care under the guidelines. Many of these patients also needed skilled care. In fact, as Table IV.4 indicates, only six patients needed semi/unskilled care **only** according to both the screening procedures and the guidelines.

Table IV.5 indicates that the skilled care guidelines applicable to the false-negative cases are guidelines which involve either the drawing of blood, which may be provided by a laboratory technician or a physician (venipuncture and coumadin monitoring), or care that is often provided by a physician (medication supervision, pain management, or follow-up professional monitoring). Almost half of the false negative cases involve the Medication Supervision Guideline. As was discussed in Section **IV.A.1,** the screening procedures for skilled care were designed to identify patients who needed

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TABLE IV.5

DISTRIBUTION OF TRUE POSITIVE AND
FALSE NEGATIVE CASES ACROSS GUIDELINES:
SKILLED CARE

Guideline[a]	False Negative		True Positive	
	Number[b]	Percent	Number[b]	Percent
Diabetic Care (10)	-	-	13	3.3
Amputation Care (11)	-	-	3	0.8
Eye Care (12)	-	-	2	0.5
Chest Physical Therapy (13)	-	-	-	
Oxygen (14)	-	-	4	1.0
Aerosol Therapy (15)	-	-	15	3.8
Tracheostomy Care (16)	-	-	-	
Monitoring Cardiopulmonary Status (17)	-	-	28	7.2
Venipuncture (18)	4	26.7	21	5.4
Coumadin Monitoring (19)	1	6.7	11	2.8
Medication Supervision (20)	7	46.7	132	33.7
IV Antibiotics and Chemotherapy (peripheral line) (21)			2	0.5
IV Pain Medication (peripheral line) (22)	-	-	2	0.5
IV Therapy (central venous line) (23)	-	-	2	0.5
Nasogastric Tube (24)	-	-	-	
Gastrostomy, Jejunostomy (25)	-	-	1	0.2
Dysphagia Management (26)	-	-	1	0.2
Urinary Incontinence Management (27A)	-	-	5	1.3
Intermittent Catheterization (27B)	-	-	1	0.2
Foley, Suprapubic Catheter (28)	-	-	1	0.2
Condom Catheter (29)	-	-	-	
Nephrostomy Tube (30)	-	-	-	
Bowel Incontinence Management (31)	-	-	2	0.5
Ostomy Care (32)	-	-	3	0.8
Wound Care (33)	-	-	12	3.1
Care of Bedbound Patients (34)	-	-	6	1.5
Care of Comatose Patients (35)	-	-		
Mobility Therapy for Chairbound Patients (36)	-	-	14	3.6
Mobility Therapy for Impaired Ambulation (37)		-	20	5.1
Knee Surgery (38)		-	6	1.5
Hip Surgery (39)		-	4	1.0
Upper Extremity Paralysis (40)	-	-		-
Pain Management (41)	2	13.3	32	8.2
Cast Care (42)		-	1	0.2
Psychiatric Monitoring (43)		-	3	0.8
Follow-up of the Cognitively Impaired (44)	-	-	6	1.5
Follow-up Professional Monitoring (45)	1	6.7	39	10.0
Total Observations	15	100.0[c]	392	100.0[c]

NOTE: Multiple guidelines may apply to the same sample metier.

*The numbers in parentheses refer to the guideline number.

[b]The number of times that the guideline was applicable.

[c]Does not add to 100 percent due to rounding.

TABLE IV.6

DISTRIBUTION OF TRUE POSITIVE AND
FALSE NEGATIVE CASES ACROSS GUIDELINES:
SEMI/UNSKILLED CARE

Guideline[a]	False Negative		True Positive	
	Number	Percent	Number	Percent
Help with summoning assistance (1)	1	7.7	39	4.7
Help with eating (2)	--	--	34	4.1
Help with bed/chair transfer (3)	--	--	73	8.8
Help with dressing (4)	5	38.5	141	16.9
Help with medicines (5)	2	15.4	155	18.6
Help with walking (6)	—	—	69	8.3
Help with bathing (7)	1	7.7	95	11.4
Help with toileting (8)	--	—	76	9.1
Help with meal preparation (9)	4	30.8	150	18.0
Total observations	13[b]	100.0[c]	832	100.0[c]

NOTE: Multiple guidelines may apply to the same sample member.

[a]The numbers in parentheses refer to the guideline number.

[b]Includes guidelines applicable to three members who needed semi/unskilled
care only and-to five sample members who needed both skilled and
semi/unskilled care.

[c]Does not add to 100 percent due to rounding.

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professional nursing or therapy. All of the false negative cases for skilled care involve guidelines for care that is often provided by persons other than nurses or therapists.

After we developed the screening procedures, we revised the guidelines to add follow-up visits to a physician. Clearly, the screening procedures must also be revised to include such visits explicitly. We should probably also revise the screening procedures to include patients who need only routine laboratory tests. It would be relatively easy to add questions on laboratory tests and follow-up physician visits to the screening instrument. An examination of the data for each of the 12 false negative cases involving skilled care indicates that the inclusion of questions on the receipt of these two types of care would substantially reduce the incidence of false negative cases: 8 of the patients in the 12 false negative cases reported receiving blood tests or making a follow-up physician visit in the two-week interview.[15] Nevertheless, relying on questions on receipt does not appear to be sufficient: four false negative cases remain for which skilled care guidelines were set that would still be screened out even with these additional questions. Moreover, questions on receipt would tend to overlook patients who did not receive needed care.

Questions' on orders for laboratory tests and follow-up physician care could also be included in the screening instrument. The hospital records of all the patients in the four remaining false negative cases contained orders

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[15]Among the five patients for whom guidelines on blood drawing were applicable, one reported receiving blood tests and three others reported making follow-up physician visits. It is possible that blood was drawn during these visits but not reported. Among the seven patients for whom guidelines on follow-up physician visits were applicable, four reported making doctor visits.

for blood tests or follow-up physician visits. However, because the interviews did not include questions on the presence of orders, we could not use the pilot study data to assess the likely success of questions on orders at ensuring the inclusion of false negative cases.[16] In any event, because patients may not be aware of the care that has been ordered for them, including questions on orders would likely be only partially successful.

Given that the Medication Supervision Guideline was applicable for almost half of the false negative cases, including a question in the screening instrument on the number of medications taken at discharge might also be helpful. However, although three of the four remaining false negative cases for skilled care involve the Medication Supervision Guideline, none of these patients (or their proxies) reported enough medications for that guideline to be applicable. In each of these cases, the hospital records listed more medications that were to be taken at discharge than were reported in the interviews. (If both hospital record and interview data on the number of medications are available, the hospital record data would be preferred under our procedures.)

While the addition of questions on laboratory testing, routine physician care, and perhaps medications would greatly reduce the number of patients screened out as not needing care when skilled care was needed according to the guidelines, such additional questions would not likely be a perfect solution. Some false negative cases would probably remain. However, semi/unskilled guidelines were applicable to some of the twelve false negative cases, and it is possible that some of them might have been screened in (albeit for the

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[16]The interviews contained a question on whether any blood tests were ordered that did not take place.

wrong type of care) if the screening indicators for semi/unskilled care had been revised.

False **Negative** Cases: Semi/Unskilled Care.   Table IV.6 indicates that two types of problems were involved in the false negative cases for semi/unskilled care. Of the 13 semi/unskilled guidelines that **were** applicable to the 15 false negative cases, over half involved types of personal care (summoning assistance, dressing, and bathing) that were not considered separately in the screen but rather were combined in a general question that asked about assistance with other personal care tasks.   Thus, the addition of separate items on these tasks would reduce the number of false negative cases.

By coincidence, the three types of personal care that were not considered separately and were involved in the false negative cases are also the three types of personal care for which adverse outcomes are not specified under the guidelines.   (Only minimally adequate amounts of care are specified for these guidelines.)   Specifying amounts of care, but not outcomes, is inconsistent with the fact that the guidelines are designed to define levels of care that are minimally adequate to prevent adverse outcomes. Therefore, unless adverse outcomes can be added for these three guidelines, it might be preferable to delete them altogether.   If these guidelines were deleted, it would not be necessary to add questions on these tasks to the screen.   This course would have the advantage of limiting the additional questions to be added to the screening interview.

The remaining false negative cases in which semi/unskilled guidelines were applicable involved the guidelines for help with medicines and meal preparation.   These cases appear as false negative cases due to an error in

the portion of the code for the screening interview which identified patients who were impaired in these activities. There were several circumstances in which patients were to be treated as impaired in these activities. A check for a relatively rare circumstance was inadvertently omitted from the code.[17] The code for the application of the guidelines was correct and allowed this circumstance to be included, thus accounting for the discrepancy between care needs according to the screen and care needs according to the guidelines.

Percentage of False Negatives under Revised Procedures. It is clear that the percentage of false negative cases under the current screening procedures can be substantially reduced by correcting the code for the screening interview and including additional questions in the screening interview. Correcting the code would be trivial. At issue is the effect of including additional questions on the length of the screening interview. For skilled care, the additional questions would cover the receipt of routine follow-up physician care and laboratory testing. For semi/unskilled care, the additional questions would cover impairment in activities not presently covered on an activity-specific basis--bathing, dressing, toileting, and summoning assistance. Questions on bathing, dressing, and summoning assistance would be added to the screening interview only if the guidelines for these activities were retained.

If the code had been correct and the questions discussed above had been included in the screening procedures, all but three of the patients in the

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[17]Patients who reported carrying out an activity alone and who reported that doing so was very painful or exhausting or took an extremely long time were to be treated as impaired if they lived alone. However, this line of code was omitted from the program for the screening interview.

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fifteen false negative cases would have been screened in.[18] The three remaining false negative cases represent an error rate of 12.5 percent among cases screened out. However, with a sample of 24 cases, the confidence interval around this estimate is large; the 95 percent confidence interval ranges from 0 to 26 percent. From a larger perspective, the three remaining false negative cases represent about 1.1 percent of all cases who needed care under the guidelines. The 95 percent confidence interval ranges from 0 to 2.3 percent.

Because additional questions on laboratory tests, physician follow-up visits, and personal care would encompass care received, further questions should be designed to identify patients who need care but do **not** receive it. One approach to such questions would be to ask about orders for follow-up physician care or laboratory tests. The patients in the three remaining false negative cases had orders for follow-up physician care or blood tests in the two weeks after discharge. While we would expect that the reports of patients about orders for care would be considerably error-prone, some patients would be able to report them correctly. If we assume that one patient in three would correctly report having such orders, we would be left with a total of two false negative cases, for an estimated error rate of 8.3 percent **(2/24).** Another approach would be to include a question on the number of medications taken at discharge. Although this question would not have been helpful with the three remaining false negative cases in the pilot study, it might be helpful in a national study.

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[18]We are assuming that the responses on these items in the revised screening interviews for these patients would be the same as those in their two-week interviews.

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False Positive Cases.   Returning to Table IV.4, we note that in only eight cases were patients identified by the screening procedures as needing skilled care (five patients) or semi/unskilled care (three patients) but were determined not to need either type of care according to the guidelines. These are false positive cases, and they represent only 3 percent **(8/265)** of the patients screened in as needing care.   This estimate is reasonably accurate. The 95 percent confidence interval around this estimate ranges from 1.0 to 5.0 percent.   Clearly, the screening procedures did not lead us to collect a large amount of data that were ultimately of no use in the analysis. This is not surprising, since the guidelines cover a broad scope of types of care.

Tables IV.7 and IV.8 present the distributions of screening indicators for the false positive cases identified by the screening procedures as needing skilled care (Table IV.7) and semi/unskilled care (Table IV.8).   Table IV. 7 also presents the distribution of the screening indicators for true positive cases for skilled care (that is, patients screened in as needing skilled care to whom the skilled care guidelines were applicable.)   Table IV.8 also presents the distribution of the screening indicators for true positive cases for semi/unskilled care (that is, patients screened in as needing semi/ unskilled care to whom the semi/unskilled guidelines were applicable).

As Table IV.7 indicates, the most common indicator of skilled care applicable to false positive cases is the presence of a condition or procedure which typically required skilled care.   Because these conditions and procedures do not necessitate skilled care in every case, it is not surprising that this indicator was applicable to patients determined not to need skilled care under the guidelines. In addition, each of the indicators on the receipt

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TABLE IV.7

SCREENING INDICATORS FOR SKILLED CARE FOR FALSE POSITIVE
AND TRUE POSITIVE CASES

Screening Indicator of Need for Skilled Care	True Positive[b]		False Positive	
	Number	Percent	Number	Percent
Had condition or procedure that typically requires post-hospital care	196	49.3	5	71.4
Received nursing or therapy[a]	101	25.4	1	14.3
Age 85 or older	31	7.8		
Physician referral for formal nursing or therapy	26	6.5	1	14.3
Institutionalization[a]	4	1.0		
Unscheduled hospital readmission or unscheduled emergency room or urgent care center visit[a]	33	8.3		
Death[a]	6	1.5		
Total (observations)	397	100.0[c]	7	100.0

[a]Refers to the two-week period following discharge.

[b]A total of 121 patients showed true positives for skilled care; a total of 387 screening indicators applied to these patients.

[c]Does not add to 100 percent due to rounding.

TABLE IV.8

SCREENING INDICATORS FOR FALSE POSITIVE AND
TRUE POSITIVE CASES OF THE NEED FOR SEMI/UNSKILLED CARE

Screening Indicator of Need for Semi/Unskilled Care	True Positive[a]		False Positive	
	Number	Percent	Number	Percent
Physical Impairment				
Eating[b]	57	6.5		
Transfer[b]	105	11.9		
Other personal care	138	15.6		
Medication administration	150	17.0		
Meal preparation	152	17.2		
Cognitive or Emotional Impairment	76	8.6		
Received Personal Care	166	18.8	3	100.0
Perceived Unmet Need for Personal Care	38	4.3		
Total (observations)	882	100.0[c]	3	100.0

[a]As determined by the guidelines.

[b]Eating and transfer were asked separately from other personal care tasks because they were to be applied in risk classification. Transfer was later dropped as a criterion for risk classification.

'Does not add to 100 percent due to rounding.

of nursing or therapy or a physician's referral to nursing or therapy were applicable in one false positive case.

As Table IV.8 indicates, only one screening indicator for semi/unskilled care was applicable in the false positive cases: the receipt of personal care. The data in this case are inconsistent. Although no impairment was reported, the receipt of personal care was reported.

Inconsistency in the Type of Care Needed. There were also some patients for whom the tvoe of care that was needed according to the screen was inconsistent with the type of care needed according to the guidelines. Unlike the false positive cases, collecting data on these cases proved to be fruitful for the analysis ; these patients needed care and were usefully included in the analysis. [19]

An inconsistent classification of the type of care occurs for a total of 39 patients, or about 15 percent (39/265) of the patients screened in as needing care. Among these 39 patients, 28 patients were identified by the screening procedures as needing skilled care but were determined to need only semi/unskilled care under the guidelines. All were identified on the screen as needing both semi/unskilled and skilled care. The screening procedures identified 11 patients who needed only semi/unskilled care but whom the guidelines- identified as needing skilled care. The types of guidelines applicable to these patients are very similar to the skilled care guidelines applicable to the false negative cases. Of the 15 cases in which skilled guidelines were applicable, all but three involved guidelines on laboratory

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[19]However, if the sample in a national study were stratified according to the type of care needed, it would likely be necessary to weight such cases in the analysis to adjust for differential selection probabilities.

tests or routine follow-up physician care. Thus, if the screen were revised to identify the need for these types of care, the number of inconsistent cases would also decline substantially.

B. CLASSIFYING PATIENTS BY THE RISK OF CARE THAT DID NOT MEET GUIDELINES AND ADVERSE OUTCOMES

The risk classification procedures were designed to support the pilot study analyses by efficiently identifying a large enough sample of patients who actually experienced care that did not meet the guidelines and who suffered adverse outcomes. In particular, these procedures identified patients at **high risk** of experiencing care that did not meet the guidelines and of suffering adverse outcomes so that they could be oversampled.

In this section, we first describe our procedures for risk classification and the variables used as indicators of risk. The remainder of the section presents our results on the effectiveness of the risk classification procedures in identifying patients who actually experienced care that did not meet the guidelines and who suffered adverse outcomes.

1. Classification Procedures

Two types of risk are at issue with respect to the adequacy of post-hospital community care: the risk of receiving care that does not meet the guidelines, and the risk of suffering adverse outcomes. In the pilot study, we were interested particularly in patients who were at high risk of experiencing care that did not meet the guidelines **and** of suffering adverse outcomes, because it is for such patients that we would most likely be able to link inadequate care to the consequences of that inadequacy: such patients

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would be the most likely to have experienced care that did not meet the guidelines and consequently to have **suffered adverse outcomes.**[20] The risk of suffering an adverse outcome involves physiological vulnerability. However, if in selecting our sample we had considered only physiological vulnerability, we would have selected many persons who were vulnerable but well cared for and who were thus unlikely to suffer adverse outcomes because they experienced care that did not meet the guidelines. Conversely, if we had considered only the risk of experiencing care that did not meet the guidelines, we would have selected many persons who were not vulnerable and thus suffered no adverse outcomes despite the lack of adequate care.

Our goal in classifying patients as at high risk (or not) was **not** the same as our goal in identifying those who needed care. In the latter case, we had planned to screen out those who did not need care: they were not followed **further.**[21] Therefore, we could tolerate few false negative cases. In contrast, we could tolerate more error as we classified patients as at high risk or not. Patients who were not at high risk were also sampled. Our goal was to classify patients well enough so that oversampling those identified as at high risk would substantially improve our "hit" rate in identifying **patients** who actually experienced care that did not meet the guidelines and

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[20]**Such** patients would be at high risk of suffering adverse outcomes **given** that they experienced care that did not meet the guidelines--that is, at high risk of adverse outcomes <u>conditional</u> on experiencing care that did not meet the guidelines. However, at least for our proposed measures of physiological vulnerability, individuals who are at highest risk of suffering adverse outcomes <u>in general</u> would also tend to be those at greatest risk of suffering adverse outcomes conditional on experiencing care that did not meet the guidelines.

[21]**The** subsample who was followed in the pilot study to help assess the effectiveness of the screening procedures was an exception.

who suffered adverse outcomes (relative to the hit rate that would have been realized had we selected a proportional sample of the population).

a. The Risk of Exoeriencinn Care That Did Not Meet the Guidelines

We hypothesized that the receipt of adequate and timely post-hospital community care depends on four underlying factors:

o The availability of formal services

o The availability and resilience of informal services (that is, care from family members and friends)

o Whether arrangements for services were made prior to discharge

o The amount of services required

These four underlying factors affect whether services are in place upon discharge, whether problems are identified and resolved, and whether services are adapted to changing conditions. The indicators of risk that we identified as important to these four factors are among those listed in Table IV.9. They are predictive indicators, based on the patient's characteristics.

In addition to these predictive indicators, the table also includes three indicators which suggest that problems with the receipt of care may have occurred. These problem indicators involve serious health problems reported (by the patient or proxy) to be associated with an unmet need for care.

The decision to use both predictive and problem indicators was a very pragmatic one. By combining the two approaches, we expected to create a better opportunity to identify those who were at risk.

As Table IV.9 shows, we developed two sets of indicators: one set for patients who needed **only** semi/unskilled care, and one set for patients who

TABLE IV.9

INDICATORS **OF THE RISK OF EXPERIENCING**
SKILLED AND SEMI/UNSKILLED CARE THAT DID NOT MEET THE GUIDELINES

Variables Used to Classify Patients at High Risk of Skilled Care That Did Not Meet Guidelines

Predictive Indicators

- 0 Living arrangement and provision of informal care[a]
- 0 Severe cognitive, emotional, or functional impairment[b]
- o Primary informal caregiver was exhausted'
- o Discharge planner did not arrange for post-discharge services while
  patient was hospitalized, **and when** help in arranging services was perceived as
  needed[d]

Problem Indicators

- o Reported serious health problems due to unmet need for help with medical
  treatments
- o Referred by doctor for post-hospital care from health care professional
  but unable to arrange services

Variables Used to Classify Patients at High Risk of Semi/Unskilled Care That Did Not Meet Guidelines

Predictive Indicators

- 0 Living arrangeamnt and provision of informal care[a]
- 0 Severe cognitive, emotional, or functional impairment[b]
- o Primary informal caregiver was exhausted'
- o Discharge planner did not arrange for post-discharge services while patient
  was hospitalized **and when** help in arranging services was perceived as needed[d]
- o Resided in rural area[e]
- 0 Low income'

Problem Indicator

- o Reported serious health problems due to unmet need for help with personal care

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[a] Divided into three categories: (1) the patient had a live-in formal or informal caregiver who was able to provide care and who did not leave the patient alone for more than 10 hours per day, (2) the patient had no able live-in caregiver but had a visiting informal caregiver who provided care on a regular basis, and (3) the patient had no able live-in or visiting caregiver.

[b] Impairment in eating, or need for constant supervision due to mental or emotional problems. Impairment in transfer was originally intended to indicate severe impairment; however, the measure of impairment at discharge appeared to be picking up temporary impairment associated with acute illness and procedures (e.g., surgery) performed during the hospital stay. The transfer criterion was dropped from the revised risk classification criteria.

'Live-in caregiver's sleep was interrupted almost every night to provide care, or caregiver (either live-in or visiting) reported being totally overwhelmed and exhausted.

[d] Originally, the lack of discharge planning alone was required to indicate the risk of inadequate care: however, this criterion was found to be too lax, as many patients did not require service arrangements through a discharge planner.

giving in a town or city of less than 5,000 people and 5 miles or more away from such a town or city.

'Patient (and spouse, if married) had income of less than $1,000 per month.

needed skilled care regardless of whether they also needed semi/unskilled care. Because semi/unskilled care is available under Medicare when the patient is receiving skilled care under Medicare, the indicators for skilled care were applied to patients who needed both skilled and semi/unskilled care.

Several of the indicators are identical for patients who needed skilled care and those who needed semi/unskilled care. For example, living arrangements and arrangements for informal care affect the availability of informal care, whether the patient needs skilled care or only semi/unskilled care. Severe cognitive, motional, and functional impairment affect the amount of services, both formal and informal, that are required. While much of the care required by severely impaired patients will be semi/unskilled care, such patients will be able to provide little or no self-care for simple medical procedures and may thus require more skilled care than do patients who are not severely impaired. The exhaustion of caregivers affects the resilience of the informal care system and thus the ability of caregivers both to provide semi/unskilled care and to learn to provide medical treatments under the instruction of skilled care providers. The receipt of discharge planning prior to discharge is an indicator of the availability of formal services, particularly immediately after discharge.

Along. with the predictive indicators common to skilled and semi/unskilled care are two additional predictive indicators for semi/unskilled care: low income and living in a rural area. We did not include income as an indicator of risk for patients who needed skilled care because many of the patients in our sample would have met the requirements for skilled home care coverage under Medicare, and their incomes would not have affected their

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access to this care. Living in a rural area was included as a risk factor for semi/unskilled care because patients living in rural areas often experience difficulty in obtaining formal, semi/unskilled services due to the limited labor markets in rural areas. The predictive indicators and the problem indicators were used in a two-step procedure to classify patients according to the risk of inadequate care. First, we considered all the combinations of the predictive indicators and assigned a high, moderate, or low level of relative risk to each combination. The combinations and the level of risk assigned to each are presented in Figures IV.1 and IV.2. In the figures, combinations with a high level of risk are marked with an "H"; those with a moderate level of risk are marked with a "M"; and those with a low level of risk are marked with an "L". For example, a patient who had an able live-in caregiver, who was severely impaired, and who did not receive discharge planning (when it was necessary) was classified as at high risk regardless of whether or not his/her caregiver was exhausted. We differentiated between moderate- and low-risk levels to permit reclassifying patients at the moderate-risk level if the high-risk group proved to be too small to support the planned analyses. But this problem did not arise.**

The problem indicators of risk were treated individually. A patient who experienced serious health problems due reportedly to unmet need was classified as at high risk regardless of the values of the other indicators.

Tables IV.10 and IV.11 present the distributions of the predictive and problem indicators in the screening sample and the analysis sample.

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[22]In Chapter **V**, we also use the term "moderate" to refer to patients who were classified as at high risk of both care that did not meet the guidelines and adverse outcomes under the original risk classification procedures, but not under the revised procedures.

FIGURE IV.B.1

RISK OF EXPERIENCING CARE
THAT DOES NOT MEET GUIDELINES:

SKILLED CARE NEEDED

Able Live-In Caregiver								Able Visiting Informal Caregiver								No Able Informal Caregiver			
Severe Cognitive, Emotional, or Physical Impairment?								Severe Cognitive, Emotional, or Physical Impairment?								Severe Cognitive, Emotional, or Physical Impairment?			
YES				NO				YES				NO				YES		NO	
Discharge Planning?								Discharge Planning?								Discharge Planning?			
YES		NO		YES		NO		YES			NO		YES		NO	YES	NO	YES	NO
Caregiver Exhaustion?								Caregiver Exhaustion?											
YES	NO	YES	NO	YES	NO	YES	NO	YES	NO		YES	NO	YES	NO	YES	NO			
H	M	H	H	M	L	H	M	H	C/E=H ADL=M[a]		H	H	M	L	H	H	H	H	L	H

NOTE: Includes patient needing skilled care only and both skilled and semi-unskilled care.

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      LEGEND:
H   =   High
M = Moderate risk
L = Low risk
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[a] Those who need supervision for cognitive or emotional impairment are at high risk.
Those who have physical impairments (ADL) are at moderate risk.

FIGURE IV. B. 2

RISK OF EXPERIENCING CARE
THAT DOES NOT MEET GUIDELINES:
ONLY SEMI/UNSKILLED CARE NEEDED

Able Live-In Caregiver								Able Visiting Informal Caregiver								No Able Informal Caregiver			
Severe Cognitive, Emotional, or Physical Impairment?								Severe Cognitive, Emotional, or Physical Impairment?								Severe Cognitive, Emotional, or Physical Impairment?			
YES				NO				YES				NO				YES		NO	
Discharge Planning?								Discharge Planning?								Discharge Planning?			
YES		NO		YES		NO		YES		NO		YES		NO		YES	NO	YES	NO
Caregiver Exhaustion?								Caregiver Exhaustion?											M
YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO				If med. or meals H[a]
H	M	H	M	M	L	M	L	H	H	H	H	M	L	M	L	H	H	L	
If Also Low Income or Rural Patient:																			
H	M	H	M	M	L	M	L	H	H	H	H	M	L	H	M	H	H	M	H

NOTE: Patients needing skilled care, as well as semi/unskilled care, are classified by risk levels associated with skilled care needs. This is because the presence of skilled care typically makes semi/unskilled care available (through Medicare).

LEGEND:
H = High risk
M = Moderate risk
L = Low risk

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[a] Those needing help with meal preparation or taking medicines will require help shortly after discharge and thus are considered at higher risk than those whose care requirements involve bathing or dressing and are less urgent. Note that those who require assistance with eating are considered to be severely impaired and are considered elsewhere in this classification scheme.)

TABLE IV. 10

DISTRIBUTION OF INDICATORS OF THE RISK OF EXPERIENCING SKILLED CARE
THAT DID NOT MEET THE GUIDELINES

Indicator	Screening Sample		Analysis Sample	
	Number	Percent of Patients	Number	Percent of Patients
Skilled Care: *				
Living arrangement and provision of informal care				
Live-in caregiver	512	72.0	176	70.1
Live-out caregiver	86	12.1	36	14.3
Neither	99	13.9	38	15.1
Severe cognitive, emotional, or functional impairment	157	22.1	110	43.8
Primary informal caregiver was exhausted	215	30.2	126	50.2
Discharge planner did not arrange for post-discharge services while patient was hospitalized&when help in arranging services was perceived as needed	133	18.7	83	33.1
Reported serious health problems due to unmet need for help with medical treatments	3	0.4	2	0.8
Referred by doctor for post-hospital care fran health care professional but unable to arrange services	61	8.6	30	12.0
Sample size (patients)	711'		251[b]	-

NOTE: Multiple indicators may apply to the same sample member.   Patients screened out as not needing care were excluded.

[a]A total of 1,266 skilled care indicators are applicable to 711 patients in the screening sample.

[b]A total of 601 skilled care indicators are applicable to 251 patients in the analysis sample.

TABLE IV. 11

DISTRIBUTION OF INDICATORS OF THE RISK OF EXPERIENCING
SEMI/UNSKILLED CARE THAT DID NOT MEET GUIDELINES

	Screening Sample[a]		Analysis Sample[b]	
		Percent		Percent
Indicator	Number	of Patients	Number	of Patients
Semi/Unskilled Care:[b]				
Living arrangement and provision of informal care:				
Live-in caregiver	68	81.0	18	81.8
Live-out caregiver	12	14.3	3	13.6
Neither	3	3.6	1	4.5
Severe cognitive, emotional, or functional impairment	15	17.9	6	27.3
Primary informal caregiver was exhausted	27	32.1	8	36.4
Discharge planner did not arrange for post-discharge services while patient was hospitalized __ and when help in arranging services was perceived as needed	15	17.9	3	13.6
Resided in rural area	15	17.9	2	9.1
Low income	14	16.7	3	13.6
Reported serious health problems due to unmet need for help with personal care	0	0.0	0	0.0
Sample size (patients)	84"		22[b]	

NOTE: Multiple indicators may apply to the same sample member. Patients screened out as not needing care were excluded.

[a]A total of 169 semi/unskilled indicators are applicable to 84 patients in the screening sample.

[b]A total of 44 semi/unskilled indicators are applicable to 22 patients in the analysis sample.

b. <u>Risk of Adverse Outcomes</u>

Our approach to assessing the risk of suffering adverse outcomes also combined predictive indicators based on the patient's characteristics and problem indicators reflecting actual post-discharge experience. The indicators of adverse outcomes are listed in Table IV.12.

As described earlier, the risk of suffering adverse outcomes reflects physiological vulnerability. We treated patients as physiologically vulnerable if they were very old (85 years or older), if their functioning was so severely impaired that they were unable to eat independently, or if they were severely ill. Several indicators were used for the presence of a severe illness. Two of the indicators of severe illness--an advanced stage of illness and a moderate stage of illness but with substantial comorbidities-- were based on the automated version of the Disease Staging measure of the severity of illness. This automated version relies on condition and procedure codes from medical records. Because these codes were not available for all patients when sample intake and screening occurred, we included other indicators of severe illness which relied on information collected in the sample member screening interview. These indicators are multiple hospital admissions and a diagnosis of congestive heart failure or chronic obstructive pulmonary disease. Patients with those particular diagnoses were included because stabilizing them would tend to be difficult.

The problem indicators for the risk of adverse outcomes are death, unscheduled readmission to the hospital, and institutionalization during the two weeks after discharge. It should be noted that the fact that a patient experienced one of these problem indicators does not necessarily mean that he

TABLE IV.12

INDICATORS OF THE RISK OF SUFFERING
ADVERSE OUTCOMES

Predictive Indicators

Age Over 85

Severe Functional Impairment (Unable to Eat Independently)

Severe Illness

Presence of a disease with systemic complications or problems of a severe nature (Stage 3 of the Disease Staging algorithm applied to that patient's condition and procedure codes)[a]

Presence of a significant comorbidity (if Stage 2)[b]

Diagnosis of congestive heart failure or chronic obstructive pulmonary disease

Two or more hospital admissions in six months prior to sample intake (includes intake admission)

Problem Indicators

Death

Unscheduled Readmission (for Any Cause)

Institutionalization (for Any Cause)

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[a]Automated Disease Staging algorithm. Stage III is defined as multiple site involvement; generalized systemic involvement; poor prognosis.

[b]Automated Disease Staging algorithm. Stage II is defined as problems limited to an organ or system: significantly increased risk of complications.

or she suffered an adverse outcomes under the guidelines. The adverse outcomes of the guidelines are linked specifically to the patient's condition. The screening indicators are not so linked. For example, an unscheduled admission may have been associated with a condition that was new for that patient, as a stroke in a patient with no history of stroke.

Table IV.13 presents the distribution of the screening sample and the analysis sample on the indicators of the risk of adverse outcomes.

c. Implementing the Risk Classification Procedures

The risk classification procedures that are described above are the final version of these procedures. The original procedures in use at the time the data collection began differed somewhat. As data collection progressed, it became clear that the proportion of patients being classified as at high risk under the original procedures was considerably higher than we had anticipated a priori, thus suggesting that the classification process might have been overstating the degree of risk, at least for some patients. If this were true, oversampling the high-risk group (identified under the original procedures) would not have produced a sufficient sample of patients who actually experienced care that did not meet the guidelines and who suffered adverse outcomes. Consequently, we reviewed the values of the risk indicators for the patients screened in the early days of the fielding, as well as the definitions of these indicators, to identify problematic indicators.

Three problematic indicators were identified. Each was revised. The original and revised procedures for these three indicators are as follows:

o Under the original procedures, patients who did not receive discharge planning were treated as at higher risk of experiencing care that did not meet the guidelines, regardless of whether they perceived a need for discharge planning. Under the revised procedures, only patients who did not receive discharge planning when a need for it was perceived were treated as at higher risk.

TABLE IV. 13

DISTRIBUTION OF INDICATORS OF THE RISK OF SUFFERING ADVERSE OUTCOMES

Indicator	Screening Sample		Analysis Sample	
	Number	Percent of Patients	Number	Percent of Patients
Age Over 85	77	9.7	39	14.3
Severe Functional Impairment (Unable to Eat Independently)	86	10.9	64	23.4
Severe Illness				
Presence of a disease with systemic complications or problems of a severe nature	I37	17.2	47	17.2
Presence of a significant co-morbidity	300	37.7	113	41.4
Diagnosis of congestive heart failure or chronic obstructive pulmonary disease	201	25.3	71	26.0
Two or more hospital admissions in six months prior to sample intake	97	12.2	33	12.1
Death	8	1.0	6	2.2
Unscheduled readmission (for any cause)	32	4.0	14	5.1
Institutionalization (for any case)	7	0.9	5	1.8
Sample size (patients)	795[a]		273[b]	

NOTE: Multiple indicators may apply to the same sample member. Patients screened out as not needing care were excluded.

[a]A total of 945 indicators are applicable to 795 patients.

[b]A total of 392 indicators are applicable to 273 patients.

o Under the original procedures, patients who were impaired in transfer, as well as patients who were impaired in eating, were treated as severely physically impaired. Severe physical impairment placed a patient at higher risk of care that did not meet the guidelines and at high risk of suffering adverse outcomes. Under the revised procedures, only patients who were impaired in eating were treated as severely physically impaired.[23]

o Under the original procedures, a patient with an unscheduled visit to an emergency room or urgent care center was treated as at high risk of suffering adverse outcomes. It appeared that the effect of this indicator was to include within the high-risk group patients who were using emergency rooms and urgent care centers as sources of routine care. Because such use of emergency rooms and urgent care centers does not represent an adverse outcome, we dropped this indicator of the risk of suffering adverse outcomes from the revised procedures.

Under the revised procedures, the proportion of patients classified as at high risk was substantially less. However, by the time the revised procedures could be designed and implemented, two-week interview data had been collected on a number of patients. Some of these were classified as at high risk under the original procedures but not under the revised procedures. These patients were included in the group not at high risk. Because they were

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[23]The measures of transfer in the screening interview referred to the patient's first full day home. It appears that some patients who reported receiving assistance with transfer or experiencing difficulties in transfer on their first full day home had only temporary difficulties in transferring. For example, they may have been having temporary difficulty with transfer after abdominal surgery.

Because the intent of the indicator on severe impairment was to include individuals with long term severe impairment who would need substantially more services and who were physiologically vulnerable, we dropped transfer from the definition of severe impairment for purposes of risk classification. (Transfer was retained as an indicator of need for semi/unskilled care.)

A measure of impairment prior to admission would have captured at least some patients with long-term impairment in transfer. However, information on impairment prior to admission was included in the two-week interview, not in the screening interview, and it was thus not available for use in the risk classification.

oversampled (under the original procedures), such patients are overrepresented relative to other patients not at high risk. They were likely to be at higher risk than were the other patients in the group not at high risk.

Table IV.14 presents the distributions of the screening and analysis samples for the levels of the risk of experiencing care that did not meet the guidelines, of suffering adverse outcomes, and of both experiencing care that did not meet the guidelines and suffering adverse outcomes under the revised procedures.

2. The Results

To assess the effectiveness of the risk classification procedures, we compared the **actual** incidence of experiencing care that did not meet the guidelines and of suffering adverse outcomes for patients at high risk with the incidence for patients not at high risk. Measuring the adequacy of care and the presence of adverse outcomes required data from the two-week interview and the medical record abstract form. Measuring presence of adverse outcomes required data from the two-week interview (for weeks one through two) and **six-** week interview (for weeks three through six). These data were available for the analysis sample, but not for the screening sample. Thus, we used the analysis sample for this analysis.

Table IV.15 compares the percentages of high-risk and not-at-high-risk patients who experienced care that did not meet the guidelines and who suffered adverse outcomes during weeks one through two, using the revised procedures but without reweighting to adjust for the overrepresentation of patients at high risk under the original procedures but not under the revised

TABLE IV.14

DISTRIBUTION OF PATIENTS BY RISK CLASSIFICATION:
REVISED RISK CRITERIA

	Screening Sample		Analysis Sample	
	Number	Percent of Patients	Number	Percent of Patients
Risk of Care That Did Not Meet Guidelines				
Skilled Care Needed[a]				
High risk	169	21.2	141	51.6
Not at high risk	542	68.2	110	40.3
Semi/Unskilled Care Only Needed				
High risk	7	0.9	4	1.5
Not at high risk	77	9.7	18	6.6
Sample size (patients)	795	100.0	273	100.0
Risk of Adverse Outcomes				
At High Risk	633	79.6	241	88.3
Not at High Risk	162	20.4	32	11.7
Sample Size (Patients)	795	100.0	273	100.0
Risk of Both Care That Did Not Meet Guidelines and Adverse Outcomes				
At High Risk	159	20.0	140	51.3
Not at High Risk	636	86.0	133	48.7
Sample Size (Patients)	795	100.0	273	100.0

NOTE: Patients who did not need care were excluded.

[a]Regardless of whether semi/unskilled care was also needed.

TABLE IV.15

CARE NOT MEETING GUIDELINES AND ADVERSE OUTCOMES DURING WEEKS ONE THROUGH TWO
FOR PATIENTS AT HIGH RISK AND NOT AT HIGH RISK

REVISED PROCEDURES/CASES WITH NISSING DATA EXCLUDEO

(Not Adjusted for the Overrepresentation of Patients at High Risk Only Under Original Procedures)

Risk Level as Classified from Screening	Experiencing Care Rot Meeting Guidelines		Sample Size[a]	Suffering Adverse Outcomes		Sample Size[a]	Care Not Meeting Guidelines and Adverse Outcomes		Sample Size[a]
	Number	Percent		Number	Percent		Number	Percent	
Patient at high risk of care not meeting guidelines and of adverse outcomes	74	69.2	107	42	42.0	100	24	28.9	83
Patient not at high risk of care not meeting guidelines and of adverse outcomes	63	59.4	106	17	16.7	102	11	12.4	89
Chi square statistic		2.2			15.7***			7.2**	

NOTE: The Chi square statistic has been used to test for statistical independence between the risk classification variable and each of the three measures of care not meeting the guidelines and/or adverse outcomes.

*Patients for which we mere unable to determine whether care mat the guidelines and/or the presence of adverse outcomes were excluded.   Patients for which the screen indicated the need for care were included regardless of whether any guideline applied.   Cases for which the screen did not indicate a need for care were excluded.

*Statistically significant at $p \leq .10$.
**Statistically significant at $p \leq .05$.
***Statistically significant at $p \leq .01$.

procedures.   While the percentage of patients at high risk who experienced care that did not meet the guidelines is larger than the comparable percentage of patients not at high risk, this difference is not statistically significant.   About 69 percent of the patients at high risk experienced care that did not meet the guidelines, compared with about 59 percent of the patients not at high risk.   For adverse outcomes, a large and highly statistically significant difference exists between the two groups. About 42 percent of the patients at high risk experienced adverse outcomes, compared with about 17 percent of the patients not at high risk. In other words, those at high risk were more than two times more likely to have suffered an adverse outcome than those not at high risk.   Large and statistically significant differences also exist between these two groups of patients when we consider **both** care that did not meet the guidelines and adverse outcomes. About 29 percent of the group at high risk experienced care that did not meet the guidelines and suffered adverse outcomes, compared with about 12 percent of the group not at high risk.

Table IV.16 presents information on the percentage of patients who suffered adverse outcomes during weeks three through six.   As with adverse outcomes during weeks one through two, these results indicate that patients in the high-risk group were much more likely to have experienced care that did not meet the guidelines and to have suffered an adverse outcome.

Table IV.17 presents estimates of the percentage of the groups at high risk and not at high risk who experienced care that did not meet the guidelines and who suffered adverse outcomes during weeks one through two, **adjusted** to correct for the overrepresentation of patients classified as at

TABLE IV. 16

CARE NOT MEETING GUIDELINES AND ADVERSE OUTCOMES DURING WEEKS THREE THROUGH SIX
FOR PATIENTS AT HIGH RISK AND NOT AT HIGH RISK

REVISED PROCEDURES/CASES WITH MISSING DATA EXCLUDED

(Not Adjusted for the Overrepresentation of Patients at High Risk Only under Original Procedures)

Risk Level as Classified from Screening	Experiencing Care Not Meeting Guidelines		Sample Size[1]	Suffering Adverse Outcomes		Sample Size[a]	Care Not Meeting Guidelines and Adverse Outcomes		Sample Size[a]
	Number	Percent		Number	Percent		Number	Percent	
Patient at high risk of care not meeting guidelines and of adverse outcomes	74	69.2	107	15	18.5	81	9	11.1	81
Patient not at high risk of care not meeting guidelines and of adverse outcomes	63	59.4	106	4	4.5	89	2	2.2	90
Chi square statistic		2.2			8.4***			5.6**	

NOTE: The Chi square statistic was used to test for statistical independence between the risk classification variable and each of the three measures of care not meeting guidelines and/or adverse outcomes.

[1]Patients for which we ware unable to determine whether care met the guidelines and/or the presence of adverse outcomes were excluded. Patients for which the screen indicated the need for care were included regardless of whether any guideline applied. Cases for which the screen did not indicate the need for care ware excluded.

*Statistically significant at $p \leq .10$.
**Statistically significant at $p \leq .05$.
***Statistically significant at $p \leq .01$.

TABLE IV.17

ESTIMATED PERCENTAGE OF PATIENTS AT HIGH RISK
AND NOT AT HIGH RISK OF EXPERIENCING CARE THAT DID NOT MEET THE GUIDELINES
AND OF SUFFERING ADVERSE OUTCOMES DURING WEEKS ONE THROUGH TWO

(Adjusted for the Overrepresentation of Patients
at High Risk Only under Original Procedures)

	Experiencing Care That Did Not Meet Guidelines	Suffering Adverse Outcomes	Care Not Meeting Guidelines and Adverse Outcomes
At High Risk	69.2	42.0	28.9
Not at High Risk	51.8	14.4	12.3

high risk only under the original procedures and to include patients screened out of the pilot study but who were actually at risk. A comparison of Tables IV.15 and IV.17 indicates that the effect of overrepresenting patients classified as at high risk only under the original procedures is to blur the difference between the groups at high risk and not at high risk. The adjusted estimates indicate that about 52 percent of those not at high risk experienced care that did not meet the guidelines, compared with about 69 percent of those at high risk. Thus, **we** estimate that, if the revised risk classification procedures had been in place initially, patients in the high risk group would have been about one-third more -likely **(69/52=1.33)** to have experienced care that did not meet the guidelines than those not in the high risk group. Moreover, a difference of this magnitude would probably have been statistically **significant.**[24]

For a number of reasons (discussed in Section **V.B),** the pilot study analysis sample contains large amounts of missing data on whether care met the guidelines and adverse outcomes were suffered. Depending on the variables examined, the results in Tables IV.15 and IV.16 exclude cases in which data are missing on (1) condition, (2) whether care met the guidelines, and (3) whether adverse outcomes were suffered. Consequently, the sample sizes vary from comparison to comparison. [25] (For example, the group at high risk contains

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[24]**The** power to detect a difference of this magnitude with a sample of 100 cases in each of the two groups is about 78 (assuming a one-tailed test of size **.05).**

[25]**As discussed** in Section V.C, a condition is missing if missing data prevented us from establishing whether or not a condition was applicable to a particular patient. Both the adequacy of care and the presence of adverse outcomes were treated as missing if the condition was missing.

107 cases with complete data on condition and whether care met the guidelines, and 83 cases with complete data on condition, whether care met the guidelines, and whether adverse outcomes were suffered (during weeks one through two).

Cases with missing data have been excluded from the analyses presented to this point. As discussed in Appendix B, the exclusion of such cases may lead to an overstatement of the percentage of patients who experienced care that did not meet the guidelines and who suffered adverse outcomes. Therefore, it was important that we investigate whether the results observed in Tables IV.15 and IV.16 were affected by missing data.

One issue is whether the amount of missing data differs systematically for patients at high risk and patients not at high risk. Major differences could be due to systematic factors that differed by risk group. While differences in the amount of missing data by risk group would not necessarily have been a problem, it would have prompted us to question the assumption that patients with missing data were comparable to those with available data. We compared patients at high risk with those not at high risk in terms of the proportion of cases with missing data on (1) whether care met the guidelines; (2) whether adverse outcomes were suffered; and (3) whether care met the guidelines **and** whether adverse outcomes were suffered. The proportion of cases with missing data is somewhat higher for the high-risk cases in each of the three comparisons. The difference is greatest when one considers whether care met the guidelines and whether adverse outcomes were suffered. For example, 33 percent of the patients in the group not at high risk were missing data on both, compared with about 40 percent of the cases in the group at high risk. However, differences of this magnitude are consistent with the fact

that more guidelines were applicable to patients at high risk than to patients not at high risk. About 60 percent of the guideline observations applied to high-risk patients, yet they comprised only about 47 percent of the analysis sample. We concluded that **there** is no evidence of systematic differences in the amount of missing data by risk group.

To investigate the sensitivity of our results to our assumptions about missing data, we recalculated the percentages in Table IV.15 with cases with missing data included in the sample, under a set of rather extreme assumptions. In including these cases, we assumed that missing conditions were **not** applicable, that all patients with missing information on specifications for care experienced care that met the guidelines, and that all patients with missing information on adverse outcomes suffered no adverse outcomes.

Table IV.18 presents results comparable to those of Table IV.15, with the exception that cases with missing data are treated in the manner described above. Although the results are attenuated under these extreme assumptions, the results in the two tables lie in the same direction, and the difference in the percentages who suffered adverse outcomes in the two groups remains **large and** statistically significant.

TABLE IV.18

CARE NOT MEETING GUIDELINES AND ADVERSE OUTCOMES DURING WEEKS ONE THROUGH TWO
FOR PATIENTS AT HIGH RISK ANO NOT AT HIGH RISK

REVISED PROCEDURES/CASES WITH HISSING DATA INCLUDED

(Not Adjusted for the Overrepresentation of Patients at High Risk Only under Original Procedures)

Risk Level as Classified from Screening	Experiencing Care Not Meeting Guidelines		Suffering Adverse Outcomes		Care Not Meeting Guidelines and Adverse Outcomes		Sample Size[a]
	Number	Percent	Number	Percent	Number	Percent	
Patient at high risk of care not meeting guidelines and of adverse outcomes	74	52.8	42	30.0	24	17.1	140
Patient not at high risk of care not meeting guidelines and of adverse outcomes	63	47.4	17	12.8	11	8.3	133
Chi square statistic		0.8		11.9***		4.8**	

NOTE: The Chi square statistic has been used to test for statistical independence between the risk classification variable and each of the three measures of care not meeting the guidelines and/or adverse outcomes.

[a] Patients for which the screen indicated the need for care were included regardless of whether any guideline applied. Patients for which the screen did not indicate the need for care were excluded. Cases with missing data were included in the sample. We assume that the patients in such cases experienced care that met the guidelines and suffered no adverse outcanes.

*Statistically significant at $p \leq .10$.
**Statistically significant at $p \leq .05$.
***Statistically significant at $p \leq .01$.

V. OTHER ANALYSES

While the validity of the guidelines and the effectiveness of the screening and risk classification procedures represent the two major analytic issues in the pilot study, two other types of issues were addressed:

o Identifying possible refinements to and assessing the validity of the guidelines by comparing orders for post-hospital care (noted in hospital records) with the care prescribed under the guidelines

o Evaluating the feasibility of the data collection procedures as implemented in the pilot study and suggesting refinements to those procedures.

These issues are discussed in turn in this chapter.

A. A COMPARISON OF CARE ORDERED WITH CARE PRESCRIBED

The primary purpose of comparing orders for post-hospital care as noted in the hospital records with the care specified under the guidelines is to help refine the guidelines by identifying the specific conditions that are not currently included in the guidelines but should be and, conversely, the conditions that are currently included but should not be. Although its primary purpose **is** to support refining the guidelines, this analysis also yields additional insight **into the** validity of the guidelines.

In comparing care ordered with care specified under the guidelines, we considered **orders** for nursing or therapy, for routine follow-up care from a physician, and for wound care in the two weeks immediately following discharge.'

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[1] **Our** intent was also to include chest physical therapy, intravenous therapy, and intermittent catheterization in this analysis; however, there were no patients with orders for these types of care in the pilot study.

The sample for the comparison of care ordered and the guideline prescriptions consists of all sample members with orders for post-hospital care. We could not differentiate cases in which no care was ordered from cases for which care was ordered but no orders appeared in hospital records. Consequently, it would have been quite misleading to include cases in the analysis for which no orders were made for post-discharge care.

Even though the primary purpose of this analysis is to refine the guidelines, we considered validity (in Section V.A.l) before considering refinement; the former requires only a relatively brief discussion. In Section V.A.2, we consider the refinements suggested by our comparison of care ordered with the care specified under the guidelines.

1. The Validity of the Guidelines

We hypothesized that if the guidelines (taken as a group) provided a reasonably valid specification of minimally adequate care, patients whose hospital records contained orders for post-hospital care would also be prescribed care under the guidelines, and the amount ordered would be no smaller than the amount specified in the guideline standards. This is, in fact, what we found.

We focused on the validity of the guidelines as a group. Thus, we limited the comparison to orders for general types of care (i.e., nursing or therapy and follow-up physician care). We compared these general orders with the guideline specifications for professional care, which are present for almost all of the skilled care guidelines. Because comparisons involving orders for very specific types of care (intermittent catheterization, intravenous therapy, and wound care) would not reflect the validity of the

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guidelines as a group, they were excluded from our analysis of validity. (However, such comparisons are discussed below in conjunction with our discussion on refining the guidelines.)

a. Results

At least one skilled guideline applied to the great majority of patients with orders for post-discharge nursing, therapy, or physician care. Seventy-five of the patients in our analysis sample had orders for nursing or therapy in the two weeks following discharge. At least one skilled care guideline applied to all but eight of those patients. Thus, the guidelines prescribed skilled care for 89 percent (67/75) of the patients with orders for nursing or therapy. In addition, semi/unskilled guidelines were applicable to seven of the eight patients for whom the guidelines prescribed no skilled care. Two hundred of the 299 patients in the analysis sample had orders for follow-up physician care in the two weeks following discharge. At least one skilled guideline applied to all but 41 of these patients. Thus, the guidelines prescribed skilled care for 80 percent (159/200) of the patients with orders for routine follow-up physician care. In addition, at least one semi/unskilled guideline applied to 29 of the 41 patients for whom no skilled guidelines were prescribed.

For the cases in which information on the amount of care ordered was available, [2] the amount ordered was never smaller than the amount prescribed under the guidelines. There were seven cases in which the amount of nursing/

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[2] While information on the number of follow-up physician visits ordered was available for all but two of the patients for whom it was ordered, information on the number of nursing/therapy visits ordered was available only for 24 of the 75 patients with orders for such care.

therapy care ordered substantially exceeded the guideline prescription. These cases are among those considered below with respect to refining the guidelines.

These results support the hypothesis that, taken as a group, the guidelines provide a reasonably valid specification of minimally adequate care. This is especially true when we consider that the guidelines were designed to focus on nursing and therapy. We made no systematic attempt to develop guidelines for all types of patients who needed follow-up **physician** care in the two weeks after discharge.

2. Refinements to the Guidelines

If they were not already included in the sample for the clinical review being conducted by Boston University, the cases for which the care ordered and the care specified under the guidelines were not comparable were reviewed individually by a nurse. Specifically, the medical record abstract forms were reviewed for: **(1)** patients to whom no skilled guidelines were applicable but who had orders for follow-up physician care or nursing or therapy; and (2) patients for whom the number of nursing/therapy visits ordered substantially **exceeded** the number of professional visits prescribed under the guidelines. The nurse **also reviewed** the medical records abstract forms for patients (not included in the Boston University review) who had orders for wound care but for whom no subpart of the wound care guideline was applicable.

a. No **Applicable** Skilled Care Guidelines

The patients with orders for nursing/therapy but to whom no skilled guidelines were applicable were generally quite impaired. Similarly, some of

the patients with orders for follow-up physician care to whom no skilled guidelines were applicable were quite impaired. Others were very old. There were also some patients with complicated medical problems for whom follow-up physician visits were ordered but no skilled guidelines were applicable.

The guidelines currently prescribe follow-up professional care (which would frequently be provided by a physician) for certain surgical patients or very short- or very long-stay patients. These results suggest that it may be desirable to add additional guidelines for follow-up professional-care for patients with complex medical conditions and for patients who are very impaired or very old, and we considered doing so. Upon reflection, we do not believe that a follow-up professional visit is necessary for minimally adequate care for a patient who is old but is also not very impaired. In addition, clinicians on the project staff reviewed each of the cases with complex medical conditions and orders for a follow-up professional visit. In no case did we believe that such a visit was required for minimally adequate care.

There was one case in which nursing visits were ordered but no guidelines (either skilled or semi/unskilled) were applicable. This case involved a patient who suffered severe trauma. Since the guidelines do not currently cover severe trauma, we recommend that they be revised to do so.

There was also one case with an order for nursing/therapy for which the skilled guideline on knee surgery probably should be applicable but is not. This guideline applies only to patients who are independent in ambulation at discharge. The code for this guideline requires that the patient not be bedbound and that he or she be able to walk without human assistance. Because

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the medical records data did not enable **us** to discriminate between patients who were lifted out of bed (and thus would meet our criteria for being bedbound) and patients who had lesser amounts of human assistance in getting out of bed, we used the interview data to determine whether a patient was bedbound. However, this procedure introduced the possibility that inconsistencies would arise between the interview and the medical records data. Such inconsistencies seem to exist in this case. The interview data indicate that the patient was lifted out of bed on his/her first full, day home (which thus meets the criterion on being bedbound), while the medical records data indicate that the patient got out of bed and walked without human assistance on his/her last full day **in** the hospital.

Inconsistencies between the interview and medical records data on functioning are considered in detail in Section V.B.5 below.

b. Amount Ordered Was Substantially Greater than **Prescription**

There are several very impaired patients for whom the number of nursing/ therapy visits ordered was substantially greater than the number prescribed under the guidelines. The fact that a large number of visits were ordered in **these cases** (e.g., every day or every other day) suggests that the intent of the order may have been to secure care from a home health aide, with supervision from a nurse.

Another patient for whom the number of visits ordered substantially exceeded the guideline prescription had an existing **tracheostomy,** oxygen therapy, and a feeding **tube,** and was hospitalized for pneumonia and chronic obstructive pulmonary disease. This patient was also quite impaired. The pneumonia may have been caused by aspiration, which in turn may have been due

to poor care prior to hospitalization. Some guidelines are available to cover failures in the care of an existing condition. (An example is the guideline covering patients admitted for skin breakdown or decubitus associated with existing incontinence.) The case of the patient with pneumonia suggests that additional guidelines covering failures of existing care for **bedbound** patients may be desirable. We recommend that this issue be put to a consensus panel.

Some of the cases in which wound care was ordered but no wound care guideline was applicable involved draining or infected surgical **wounds** of the head, neck, and legs. The guidelines on surgical wounds cover only surgical wounds of the upper extremities and the trunk. These cases suggest that it may be desirable to refine the guidelines to cover surgical wounds to other parts of the body.

One case also involved a nonsurgical wound in which wound care was ordered but the wound care guideline was not applicable. This wound was a draining **hematoma** associated with an intravenous line. The subparts of the guideline covering nonsurgical wounds cover decubitus, burns, and ulcers on any part of the body and gangrene of the lower extremities. This case suggests that it might be useful to refine the guidelines to cover other types of non-surgical wounds.

The remaining **cases**[3] in which wound care was ordered but no wound care guidelines were applicable involved wounds that were apparently **not** draining

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'There was also **one case** in which a wound care guideline should have been applicable but was not because the code for that guideline was in error. Information on the size of the wound was missing in this case; this missing information made it impossible to determine which of two guidelines on wound care applied. The intent in this circumstance was to trip the guideline that prescribed the lesser amount of care as a default. However, this default condition was inadvertently omitted from the code for surgical wounds. **(It** is present in the code for non-surgical wounds.)

or infected. Professional wound care is not required if the wound is not draining or infected. Thus, no refinements of the guidelines are indicated by these cases.

B. THE FEASIBILITY OF DATA COLLECTION

In this section, we consider the data collection methodology and procedures underlying the pilot study. Our purpose is to draw lessons and suggest refinements for national study.

Overall, the data collection methodology used in the pilot -study is feasible. The methodology successfully addressed many of the potential problems that we were very concerned about as we began the pilot study. To be specific:

o We were concerned that it would be difficult to secure the voluntary cooperation of hospitals. However, over 80 percent of the hospitals that were approached agreed to participate.

o We were concerned that it would be difficult to obtain ICD-O-CM codes shortly after discharge for use in screening and risk classification. However, we were able to do so for almost 90 percent of the patients.

o We were concerned that it would be difficult to obtain and process the information necessary for identifying patients and classifying them according to the need for care and risk level in a timely manner, **so** that interviewing could begin two weeks after discharge. However, the schedule for these procedures proved **workable.**

o We were concerned that patients **and/or** their caregivers would be reluctant to participate so soon after a serious illness and that, consequently, the non-response rate would be high. However, the respondents were very cooperative, and the response rates to all the interviews were high.

o We had been concerned that we would not be able to abstract information on functioning from the medical records. However, we were able to do so for the vast majority of cases, albeit with some difficulty.

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These positive points are not to say that the data collection strategy used in pilot study did not encounter any serious problems. The major problem is, as we have discussed, the extent of missing data. We were concerned about this issue, and designed the data collection strategy whereby alternate data sources could be provided when the desired data were missing from the primary source. However, missing data remains a serious problem. The major reasons for the missing data involve problems in abstracting data from the medical records and inconsistencies between the medical records and interview data that we did not anticipate in the data collection design. In addition, the procedures for abstracting medical records data and the automated procedures for applying them must be refined substantially. The clinical reviewers identified a number of instances in which they felt that the guidelines had not been applied correctly. While it did not present a serious problem in the pilot study, obtaining signed consent forms from patients would present a potential problem for a national study. Finally, errors in the information on discharge disposition in hospital records may necessitate a minor revision to the data collection strategy.

In the remainder of this section, we consider these feasibility issues, beginning with the cooperation of hospitals, followed by scheduling, response rates, missing data, and refinements to the medical records abstraction procedures and the automated procedures for applying the guidelines.

1. Securing the **Cooperation** of **Hospitals** and **Implementing** Data Collection at **Hospitals**

In this section, we consider first the cooperation of hospitals and then the implementation of data collection at hospitals.

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a. Cooneration

Our approach to securing the agreement of hospitals to participate in the pilot study was to send the chief executive officer a personalized letter, signed by the Administrator of the Health Care Financing Administration and the Assistant Secretary for Planning and Evaluation of the U.S. Department of Health and Human Services. The letter provided a brief description of the study, focusing on the data collection in hospitals, and asked for the hospital's participation. The letter indicated that registered nurses would be collecting the data in the hospitals, and that the confidentiality of the patient and the hospital would be respected. Enclosed with the letter was a more in-depth description of the study design for the pilot study. The letter was followed by a telephone call from a senior member of the project staff.

The goal for the hospital sample was eight hospitals, four in each of the two states selected for the study. A primary sample of eight hospitals and a secondary sample of another eight hospitals were selected. Each hospital in the secondary sample was matched to a primary sample hospital that exhibited similar characteristics. All of the primary sample hospitals **were** approached, and six readily agreed to participate: two declined.

The two primary sample hospitals that declined to participate in the pilot studywere private, for-profit hospitals. We later learned that one of them was involved in a merger at the time. The other hospital later reversed its decision and agreed to participate in the pilot study after the study was discussed in a meeting among the medical staff.

When the two hospitals from the primary sample declined, we approached the matches for those hospitals in the secondary sample. One of these

hospitals readily agreed to participate. The other hospital was a member of a major, national hospital chain and the issue of participation was referred to the chain's headquarters. Officials at the chain's headquarters declined to participate on the grounds that other hospitals in the chain were already participating in another HCFA study, and that it was an unreasonable burden to participate in another. A third hospital from the secondary sample was approached and agreed to participate.

When the hospital in the primary sample that had initially declined reversed its decision, a total of nine hospitals had agreed to participate. This total represents 82 percent of the eleven hospitals whose cooperation we sought. The comments of the hospital staff suggest that they were willing to cooperate because they felt that the issues addressed by the study were important.

Hospitals serving different types of communities and with a variety of characteristics are included among the participating hospitals. They vary in terms of the availability of home health services, rural and urban setting, bed size, ownership/auspices, and membership in a chain. We selected hospitals in different settings to ensure varied environments in which patients in the pilot study would be receiving care after their discharge from the hospital. We selected hospitals that exhibited different characteristics so that problems in securing cooperation or collecting data that might be associated with a particular type of hospital would surface in the pilot study. Table V.1 presents information on the characteristics of the nine participating hospitals. Their characteristics vary considerably. The major

TABLE V.l

CHARACTERISTICS OF THE NINE HOSPITALS
PARTICIPATING IN PILOT STUDY

Characteristic	Number of Hosoitals
Size	
Small (O-99 beds)	2
Medium (100-299 beds)	4
Large (300 or more beds)	3
Ownership/Auspices	
Private, for-profit	1
Religious affiliation	4
Other private, non-profit	4
Membership in Chain	
Yes	5
No	4
Environment"	
Rural, poor service environment	1
Urban/suburban, poor service environment	2
Urban/suburban, rich service environment	2
Urban/suburban, average service environment	4

[a] Rural hospitals are those in a county which is not part of any type of metro-
politan statistical area, as defined by the U.S. Census Bureau. To charac-
terize the availability of formal services for post-discharge care, we
classified counties as rich, average, or poor based on Medicare expenditures
for home health care per aged individual.

exception is that no public hospitals are **included**,[4] and there is only one rural hospital.

With respect to cooperation, the results of the pilot suggest that the staff of many hospitals would find the issues addressed in a national study important and would agree to participate. However, these results also suggest that it may be more difficult to persuade for-profit hospitals to participate in a national study than it would hospitals that operate under other types of auspices. In addition, if the hospital is a member of a chain, it would sometimes be necessary to secure permission from officials at headquarters.

To the extent that nonparticipating hospitals differ systematically, it may be advisable to adjust the results of a national study to reflect the population of hospitals. Such adjustments for nonresponse assume that the results for nonparticipating hospitals are similar to those for participating hospitals. Thus, it would be desirable to use published data to investigate whether nonparticipating hospitals are similar to participating hospitals.

b. **Implementation**

The data collection procedures were tailored to fit the operating procedures of each hospital, so as to impose as little burden as possible on hospital staff.. For example, at one large hospital, medical records were available in automated form, and our staff used a terminal to access the information to be abstracted.

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[4] In selecting the sample for each state, we first identified a county in a metropolitan area and a rural county within driving distance. There was only one public hospital in the counties so identified. It was not selected because it was so small (20 beds) that it would have discharged only a handful of eligible patients during the sample intake period.

One concern prior to fielding the pilot study was the accuracy of the information on discharge disposition contained in hospital records. The information is used to identify patients discharged to the community and who were thus eligible for the study. In particular, we **were** concerned that some patients listed as discharged to institutions would in fact have been discharged to the community. We telephoned the next of kin listed on the hospital record for a sample of 110 patients whose hospital records indicated that they were discharged to an institution. Twelve of these patients did not enter a nursing home or another hospital immediately. Two of the twelve were residents of group facilities. The others returned to private residences, although some of them entered a nursing home within a few days. These results suggest that a national study may find it useful to verify discharge disposition if the hospital record indicates discharge to an institution, so as to be able to identify patients actually discharged to home and to include them in the study.

Another concern prior to fielding was whether hospitals would require patients to sign consent forms before releasing their names. Only one of the nine participating hospitals required consent forms. The hospital preferred that hospital staff approach patients about participating in the study. Unfortunately, only a small minority of the eligible patients in this hospital signed a consent form. Apparently, the hospital staff did not make a subsequent attempt at having the consent forms signed if patients were unavailable on the first attempt. This experience suggests that attaining high levels of patient participation would be difficult in hospitals that require consent forms in a national study.

2. <u>Scheduling</u>

Close scheduling is required to collect identifying information on
patients as they are discharged from the hospital, to collect condition and
procedure codes from their medical records, and to process this information
prior to administering an interview two weeks after discharge.

The procedure that we used to meet this schedule involved a number of
steps :

- o Hospitals were visited by MPR staff on a prearranged schedule to
     identify patients who were eligible for the study. The schedule
     was such that patients were identified from one to four days
     after their discharge.

- o The names of the eligible patients were given to medical records
     staff so that the medical records for these patients could be
     located.

- o ICD-9-CM condition and procedure codes were abstracted by MPR
     staff from the medical records, if these codes were available by
     eight days after discharge.

- o Intake forms containing patient identifying information and ICD-
     9-CM codes were shipped by overnight courier to MPR's
     headquarters.

- o The intake forms were reviewed by MPR staff to eliminate any
     ineligible cases.

- o The patient's Medicare numbers were entered into a data base to
     identify any patients already in the sample (due to an earlier
     admission) and to assign study identification numbers.

- o The intake forms were data-entered and verified.

- o The intake data were processed to assign severity of illness
     codes (based on the ICD-9-CM codes) and to initialize the
     automated file for computer-assisted telephone interviewing
     (CATI).

The number and complexity of these steps had led to concern that it would be
difficult to maintain this schedule in practice.   However, this was not the

case; for every patient selected, the CAT1 file was ready within two weeks after his or her discharge.

Maintaining the schedule and conducting the interviews as soon as possible after the first appropriate day was important because the interviews relied on patient recall for critical information. The information on the number of nursing or therapy visits and the timing of those visits relative to discharge (used to determine whether standards of care were met) was particularly subject to error as the recall period lengthened.

Table V.2 presents information on the elapsed time from the first appropriate day to the completion of the interview for all of the interviews. The overwhelming majority of the screening and six-week interviews were completed within seven days after the first appropriate day, and about 65 percent of the full two-week interviews met this standard. (It should be noted that the full two-week interview could not be completed until the screening interview had been completed for that patient.) However, it is the full two-week interview which contains the questions for which accurate short-term memory is so critical. With respect to mean elapsed days, Table V.2 shows that an average of 4.6 days elapsed between the first appropriate day for a screening interview and the completion of both screening interviews.[5] On average, another 2.6 days elapsed (7.2-4.6) from the completion of the screening interview to the completion of the two-week interview.' An average

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[5] Or until the caregiver screening interview reached final status. The completion of the caregiver screening interview was not required before classification on the need for care and risk level proceeded.

[6] Or until the caregiver two-week interview reached final status. As with the screen, the completion of the caregiver two-week interview was not required.

TABLE V.2

ELAPSED TIME TO COMPLETION
(Days)

Interview	Mean	Median	**Range**	Percent Completed within 7 Days.	Percent Completed within 14 **Days**
Screening **Interview**[a]	4.6	4	0-24	85.6	98.2
Full Two-Week **Interview**[a]	7.2	6	0-32	64.9	91.4
Six-Week Interview	2.5	1	0-20	92.6	98.6

NOTE: Measured in terms of days elapsed after the first appropriate day for the interview. For example, for the screening and two-week interviews, the fifteenth day after completionwas the first appropriate day, and it is treated as day 0 in this table.

[a]For the sample member or caregiver interview, whichever is later. It was not possible to determine which was later for an individual case. However, data on elapsed time to the initial contact indicate that the sample member screen was usually initiated before the caregiver screen, and that the caregiver two-week was usually initiated before the sample member two-week.

of 2.5 days elapsed from the first appropriate day for the six-week interview until its completion. Thus, mean elapsed days is substantially longer for the screen than for the other interviews.

Difficulties in locating a patient or a proxy respondent the first time that we attempted to reach him or her account for much of the longer elapsed time to complete the screening interviews. Another reason was that it was not always possible in the pilot study to attempt to conduct the screening interviews on the first appropriate day-- that is, the fifteenth day after the patient's discharge. Substantial turnover among the screening interviewers forced us to delay initiating some screening interviews until additional interviewers could be trained.

The task of the screening interviewer was complex, thus probably contributing to turnover in interviewers. The difficult portions of the sample member screening interview are the questions which require the interviewer to code medical condition and procedures. Interviewers had difficulty in becoming facile with medical terminology quickly. In addition, even though the list of condition codes was short, it would not fit onto a single CAT1 screen, and interviewers had to move onto the next screen if a condition was not listed. A series of such screens was required to code all the patients' conditions. Some interviewers found it difficult to move with facility through this series of screens.

In addition, many interviewers found it difficult to move with facility between the two screening interviews and the caregiver two-week interview.[7]

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[7] If the patient was selected for the two-week sample, the screening interviewer was supposed to conduct the caregiver two-week interview.

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Because interviewers did not always correctly follow **the** procedures for moving between interviews, **it** was sometimes necessary to delay completing the interview until a programmer could "reset" the skip logic in the case.

In a national study, the possibility of entering codes for conditions rather than moving between screens should be investigated. In addition, the procedures for moving among the CAT1 interviews should be reviewed to determine whether it is possible to streamline them.

In the pilot study, screening interviewers received sixteen hours of instruction. We recommend that the training be increased in the national study to at least 24 hours, with the additional day devoted to drills and exercises on coding medical condition and procedures and becoming facile with moving between the interviews. [8] This increased training should help reduce interviewer turnover.

3. Patient and Careniver **Response**

In general, the response of patients and their caregivers to the study was quite favorable . A number of them indicated that they were willing to participate because they felt that the issues addressed in the pilot study were `**quite** important.

Tables V.3 through V.6 present the distribution of final statuses for the screening, full two-week, and six-week interviews and the medical records abstraction forms, respectively. **As** indicated in the tables, the completion rates for all the interviews were quite high. The fact that only those who

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[8]**The** training times assume that the interviewers were already experienced CAT1 interviewers.

TABLE V.3

FINAL STATUSES FOR ELIGIBLE CASES:
SCREENING INTERVIEWS

Status	Number	Percent
Complete		
Both sample member and caregiver complete	705	
Sample member complete/caregiver incomplete"	141	
Total	846	88.3
Sample Member Refused	51	5.3
Sample Member Could Not Be Located[D]	32	3.3
Other Incomplete[c]	29	3.0
Total Number of Screening Interviews Attempted For Eligible Sample Members[d]	958	100.0

'Includes cases in which the sample member (or his or her proxy) reported that he or she did not have a caregiver.

These cases were screened on the need for care and were classified for risk on the basis of the sample member screen alone.

[b] Includes no answer after multiple attempts.

[c] These cases had not reached a final status when screening was discontinued because the desired sample of two-week interviews was attained.

[d] Excludes 21 screening interviews which were attempted but for which the sample member was found to be ineligible during or after the completion of the screening interview.

TABLE V.4

FINAL STATUS OF THE
FULL TWO-WEEK INTERVIEWS

Status	Number	Percent
Complete[a]		
Both sample member and caregiver complete	304	
Sample member complete/ caregiver **incomplete**[b]	68	
Total	372	88.6
Sample Member Refused	35	8.3
Sample Member Could Not Be **Located**[c]	3	0.8
Other **Incomplete**[d]	10	2.4
Total Number of Two-Week Interviews Attempted	420	100.0

"Includes two interviews completed with sample members who were later determined to be ineligible.

[b] Includes cases in which the sample member (or his or her proxy) reported that he or she had no caregiver.

Because only one of the guideline conditions involved data collected in the caregiver interviews (follow-up of the cognitively impaired), and then only as a backup to the medical records abstract data, these cases were usable for the analyses involving adequacy of care and adverse outcomes. They were missing descriptive data on caregiver burden. It should be noted that there is no regular caregiver for many cases in which the caregiver interview is not complete. Thus, caregiver burden is not an issue.

'Includes no answer after multiple attempts.

[d] These cases had not reached a final status when interviewing was discontinued because the desired sample of two-week interviews was attained.

TABLE **V.5**

FINAL STATUS OF THE
SIX-WEEK INTERVIEW

Status	Number	Percent
Complete	242	99.2
Refusal	2	0.8
Could Not **Locate**[a]	-	-
Other Incomplete	-	-
Total Number of Six-Week Interviews Attempted	244	100.0

[a]**Includes** no answer after multiple attempts.

TABLE V.6

FINAL STATUS OF THE
MEDICAL RECORD ABSTRACT

Status	Number	Percent
Complete	300	99.7
Could Not Locate Record	1	0.3
Other Incomplete	0	0.0
Total Number of Medical Record Abstracts Attempted	301	100.0

had completed a two-week interview were eligible for the six-week interview contributed to the very high completion rate for the six-week interview.

As anticipated, many of the interviews were completed by a proxy respondent. Table V. 7 presents information on the use of proxy respondents in each of the interviews for which they were allowed. [9] The percentage of interviews completed by a proxy ranges from 34 to 45 percent. Even though the full two-week sample member interview was much longer than the sample member screening interview, the use of a proxy respondent (for the entire interview) was only about 6 percentage points greater in the full two-week interview. Only a small percentage of the two-week interviews were completed by both a sample member and a proxy respondent. The use of proxy respondents was greatest for the six-week interview, probably reflecting the fact that this interview contained a number of items on out-of-pocket costs for health care. Sample members may know less than proxy respondents about such costs. In fact, sample members frequently referred us to other members of their families for this information, thus accounting for the larger percentage of six-week interviews in which both the sample member and a proxy were respondents.

4. Missing Data

We had anticipated that data would often be missing from the hospital medical records, and had designed the data collection strategy to address this problem. Backup questions to ascertain information which was likely to be missing from the medical records were included in the screening and two-week interviews. For example, the screening interview included questions on

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[9] Proxy respondents were not allowed for the caregiver screening and caregiver two-week interviews.

TABLE V.7

USE OF PROXY RESPONDENTS
(Percent)

Interview	Sample Member Only	Proxy Only	Mixed	Sample Size
Sample Member Screening Interview[a]	65.8	34.1	b	846
Sample Member Two-Week Interview[a]	56.8	39.7	3.5	370
Six-Week Interview	47.5	45.0	7.4	242

"Proxy respondents were not permitted for the caregiver interviews.

[b]Because no provision was made for special skip patterns for frail respondents, we did not maintain statistics on the number of sample member screening interviews in which a sample member respondent participated in part of the interview and a proxy respondent participated in the remainder.

medical conditions and procedures. The responses to these questions substituted for **ICD-9-CM** codes if the codes were not available at intake. Further, the two-week interview included a number of items on the nature of instruction given in the hospital which were used if no information on instruction was found when the full hospital record was abstracted.

In addition to the extensive use of backup information, a limited number of situations called for using a default procedure. This default procedure was used when missing data prevented us from determining which of a **pair** of related guidelines was applicable. In this situation, we treated the guideline which prescribed <u>less</u> care as applicable, by **default.**[10] Regardless of the true value of the missing data element, care was clearly inadequate under the guidelines when it failed the lesser standard. For example, the conditions for Guidelines **33J** and 33M differ only according to wound size. If wound size was missing, we treated Guideline **33J** (which prescribes fewer professional visits) as applicable and Guideline 33M as inapplicable. The default procedure was also used for pairs of guidelines which differed only in terms of the provision of instruction in the hospital. In the pilot study, the default procedure was applied only in a very few uses.

'Table V.8 indicates the extent to which missing data prevented us from determining:

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[10]**A** variable indicating that the guideline was set by default was also created. Our intent was to use this variable in the analysis to investigate the effect of the default procedure. However (as noted above), the default procedure was actually applied in very few cases in the pilot study, and this analysis was unwarranted.

TABLE V.8

MISSING DATA ON CONDITION, WHETHER CARE MET THE
GUIDELINES, AND WHETHER ADVERSE OUTCOMES WERE SUFFERED

Type of Care	Condition			Whether Care Ret the Guidelines[a]			Whether Adverse Outcomes Were Suffered[a]		
	Number	Percent	sample Size	Number	Percent	sample Size	Number	Percent	sample Size
Semi/Unskilled Care	56	6.0	926	200	23.0	870	76	13.2	575[b]
Skilled Care	165	27.8	593	24	5.6	428	41	9.6	428
All Care	221	14.5	1,519	224	17.2	1,298	117	11.7	1,003[b]

NOTE: The unit of observation is each guideline.

'Considers only cases in which the condition was not missing and was applicable.

[b]There are three semi/unskilled conditions for which no outcomes were specified: 295 observations on these conditions were included in assessing missing data on whether care met the guidelines, and were excluded in assessing missing data on whether adverse outcomes were suffered.

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- o Whether a patient's <u>condition</u> was -such that a given guideline applied or did not apply (e.g., whether the patient required aerosol therapy under the guidelines)

- o Whether the patient received <u>care that met the **guideline** specifications</u> (e.g., whether the patient received the number of professional visits specified in an applicable guideline)

- o Whether the patient <u>suffered an adverse outcome</u> for an applicable guideline (e.g., whether the patient suffered a fall when the transfer guideline was applicable)

Information is presented in Table V.8 separately for the skilled and semi/unskilled guidelines, as well as for all guidelines. The denominator for the percentages on condition is the sum of the observations with applicable guidelines and those for which we could not determine whether or not the patient had that condition and thus whether the guideline was applicable. The denominator for the adequacy of care is the number of observations with applicable guidelines. The denominator for outcomes is the number of observations with applicable guidelines forwhichmeasures of adverse outcomes were collected. We estimate that in 14.5 percent of all the potential observations on condition missing data prevented us from determinating whether or not a patient had a given condition. Because two guidelines or two **subdivisions** of a guideline were coded as missing when we could not determine which was applicable, this percentage over'states the number of potential observations lost. Missing data prevented us from determinating whether care was adequate or adverse outcomes suffered in about 23 percent of the cases in which condition could be determined. Overall, up to 37 percent of the <u>potential</u> observations were lost to analysis due to missing data on condition,

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adequacy of care, or adverse outcomes." The <u>actual </u>number of observations lost to analysis is unknown, but lies between 23 percent and 37 percent.

Because multiple guidelines often applied to the same patient, the problem of missing data is compounded when we consider the patient as a unit of analysis. Considering only the guidelines that we know were applicable, we were able to determine whether care met the guidelines **and whether** adverse outcomes were suffered only for 57.5 percent of the patients in the analysis sample of 299 patients. (This sample contained no patients for whom we were unable to determine whether or not at least one guideline was applicable.)

In the remainder of this section, we consider the causes of missing data.

a. <u>Condition</u>

Missing data on condition is less extensive for semi/skilled care than for skilled care. As Table V.8 indicates, missing data prevented us from determining whether a skilled guideline did or did not apply in over 27.8 percent of the relevant observations. (As noted above, each instance in which a guideline was determined to be applicable or inapplicable was counted as a relevant observation, as was each instance in which we could not determine **whether** a guideline was applicable.) In contrast, missing data prevented us

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[11]For the Basic Guidelines, 769 observations exist for which data on condition, whether care met the guidelines, and whether adverse outcomes were suffered were available. Of these, 741 were used in the analysis described in Chapter III, and the remainder were set to missing in that analysis to prevent counting a single outcome event on different guidelines (that is, to prevent double-counting). The total number of observations for which data on conditions, whether care met the guidelines, **and whether** adverse outcomes were suffered <u>could</u> be available is 1,224 (1,519 minus the 295 cases on guidelines for which adverse outcomes were not specified. Thus, our measure of the upper bound of missing data on potential observations is 37.17 percent (1-[769/1,224]).

from determining whether a semi/unskilled guideline applied in 6 percent of the observations.

The fact that the percentage of missing data is much higher for skilled care guidelines is not surprising. In general, many more data elements are required to identify conditions to which skilled care guidelines apply than to identify conditions to which semi/unskilled care guidelines apply. If **any** of these data elements are missing, we would not be able to determine whether or not the guideline applied (with the exception that, in a limited 'number of instances, we would use the default procedure described above).

As we anticipated, informationnecessary for determining which guidelines were applicable to a patient was sometimes missing from the medical record or was not abstracted due to error. ICD-9-CM codes were unavailable in time for screening for about 10 percent of patients. Fifteen percent of the items on the medical record abstraction forms were missing data for more than 5 percent of the relevant cases. The items with more than 5 percent of the relevant cases missing may be grouped into six categories:

o Whether the patient (or caregiver) received instruction in the hospital

o Whether a given condition existed prior to that hospital stay (e.g., whether or not a colostomy was new)

o Whether the patient experienced certain problems during the hospital stay (e.g., very high blood sugar)

o Detailed information on orders for post-hospital care (e.g., the schedule for ordered blood tests)

o Whether a given condition still existed at discharge (e.g., whether a wound was draining at discharge)

o Detailed information on the nature of discharge planning in the hospital (e.g., whether a physical therapist provided written material in conjunction with discharge planning)

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With the exception of the data elements on discharge planning, all of these types of data elements were used to determine whether a guideline was applicable. Unfortunately, information was sometimes available from the medical record, but was overlooked by the abstractor. This issue is discussed further in Section V.B.5 below.

b. Whether Care Met the Guidelines

In determining whether or not care met the guidelines, missing data is a much more serious problem for semi/unskilled care than for skilled care. Missing data prevented us from determining whether or not care met the guideline specification (when the guideline was applicable) for about 6 percent of the observations on skilled care guidelines, and for 23 percent of the semi/unskilled care guidelines.

The major causes of missing data on whether care met the guidelines are inappropriate skips applicable to interview items and the lack of detailed data on follow-up physician visits. To a lesser extent, the inability of a respondent to answer also led to missing data. We consider these issues in this section.

Inappropriate Skipping. Inappropriate skipping had two root causes--an error in the CAT1 code, and inconsistency between the medical records data and the interview data. The error in the CAT1 code involved the skip logic for the interviews, whereby **questions** about certain care specifications that should have been asked were sometimes skipped. Fortunately, the problem involves a rather small group of **patients--**specifically , those patients who lived alone and who performed an activity (such as transfer) alone, but for

whom doing so was very painful or exhausting or for whom the activity took an extremely long time.

Inconsistency between the medical records data and the interview data was a far more important cause of inappropriate skipping than was the error in the CAT1 code. In a sense, it is a misnomer to say that such inconsistency led to "inappropriate skipping." At the time the interview was conducted, the skip logic followed in the interview was perfectly appropriate. However, given the information later abstracted from the patient's medical record (after the interviews had been completed), such skipping was indeed found to be inappropriate.

The skip logic of the full two-week interview depended on the patient's condition as given in the medical records summary sheet and _as reported_ in the two-week interview, while the final determination of which guideline were applicable was based on data from the full medical record, supplemented by the two-week interview. [12] (It should be recalled that the full medical record was not abstracted until some weeks after the two-week interviews had been completed.)

Inappropriate skipping may have occurred for either skilled or semi/'&killed care, although it was a greater problem for the latter. Most of the specifications for skilled care involve the number and timing of professional visits, and are based on questions that were asked _regardless_ of the patient's condition: in contrast, all of the specifications for semi/ unskilled care are specific to the condition and were asked only if the available information (from the two-week interview) indicated that the

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[12]**Medical** records were not used as a source of information on condition for the semi/unskilled guidelines on summoning assistance, help with dressing, help with medicines, and help with meal preparation.

condition was applicable. The fact that inappropriate skipping was chiefly a problem for semi/unskilled care accounts for the larger percentage of observations with missing data for semi/unskilled care than for skilled care. For example, consider the guideline on help with bathing. Items on the medical records abstract form were used to determine whether the patient needed help with bathing at the. completion of his or her stay, and thus whether the guideline on help with bathing was applicable. In contrast, questions on specifications for care with bathing (that is, whether a patient had at least one full bath a week and, if not, whether it was due to a lack of assistance) were asked only if the patient or proxy reported needing or having human assistance with bathing immediately after discharge in the two-week interview. Suppose that a patient's medical record indicated that he or she had human assistance with bathing at the end of his or her stay, but that the patient reported no human assistance with bathing (in the two-week interview). In this case, the guideline on bathing would be applicable, but the questions for ascertaining whether the specification for care on bathing was met would not have been asked. Thus, in this case, we could not determine whether or not care met the specifications on bathing.

Follow-Up Physician Visits. Some of the missing data on standards of skilled care stems the fact that the two-week interview does not include questions on the number or timing of routine follow-up physician visits. (The interview does contain questions on the total number of physician visits in the two weeks immediately after discharge, whether any visits were for scheduled follow-up visits, and whether any visits were for unscheduled visits for unexpected problems.) Questions on the number and timing of follow-up

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number of professional visits **were** made or not.   However, if the same patient reported having scheduled follow-up physician visits <u>and</u> physician visits for unexpected problems, we could not determine whether the patient had one or two follow-up physician visits.   If the specified number of professional visits was two, we could not determine whether it was received.

Similarly, without information on the timing of **followup** physician visits , **it** was sometimes not possible to determine whether or not the specified care on the timing of initial visits was received.   Measuring the timing of the initial follow-up physician visit was a problem only for some of the guidelines (listed above) for which physician visits are counted. These are Monitoring Cardiopulmonary **Status**, Coumadin Monitoring, Medication Supervision, and Pain Management.   The other guidelines for which follow-up physician visits were counted toward meeting the specifications for care prescribed only a single visit within the two weeks following discharge. For these guidelines, the only issue is whether the patient had at least one professional visit during that time; the specification for timing was not applicable.

<u>The Inability of a Respondent To Answer</u>.   **As** noted above, the great majority of the specifications for skilled care involve the number of professional visits and the timing of the initial professional visit.   To determine whether the specified care was received, respondents were asked to report the number of nursing/therapy visits and their timing relative to discharge.   This information is difficult to recall (even shortly after the two-week, immediate post-discharge period).   Some respondents were simply unable to answer these questions.

c. Outcomes

Inconsistency between medical records and interview reports is the major cause of missing data on outcomes. Inconsistency is a major problem for outcomes for skilled care, because (in contrast to specifications for care) questions on skilled care outcomes were asked only if the patient had a condition to which that outcome was applicable. In addition, inconsistency led to the inappropriate skipping of outcomes for semi/unskilled care. The error in the CAT1 code discussed above also led to the inappropriate skipping of questions on outcomes for semi/unskilled care. Finally, as noted above, outcomes were deliberately set to missing to prevent counting the same event (e.g., a fall) for two guidelines.

d. Dealing with Missing Data in a National Study

As we have seen, some of the results of the pilot study are sensitive to the assumptions made about missing data. This sensitivity is a direct result of the amount of missing data. To ensure that the results of a national study are credible, it will be very important to reduce the extent of missing data substantially. We discuss ways to do so below. However, even if missing data is reduced drastically, a national study would benefit from comparing the characteristics of patients with missing data with those of patients without missing data to determine whether the former differ systematically.

Some of the problems that led to missing data in the pilot study can easily be resolved in a national study; others cannot. Correcting the CAT1 code would be a trivial procedure, as would adding questions on the number of scheduled follow-up physician visits and the timing of the initial such visit. On the other hand, it is probably not possible to effect much of a reduction

in missing data by addressing the inability of respondents to answer. However, to substantially reduce the amount of missing data, we **must** reduce the inappropriate skipping associated in the pilot study with inconsistency between the medical records and the interview reports. Procedures for resolving the inconsistencies between the interview data and the medical records data are discussed in the next section on revisions to the medical record abstraction and automated procedures.

e. Inaonrooriate **Skipping**

Inappropriate skipping due to inconsistency between the medical records and the interview reports is a fundamental problem. It can be reduced by asking more questions regardless of condition. For example, the question on the presence of a urinary tract infection could be asked for all patients, not just for those who report in the interview that they need help with toileting. A list of such outcomes could be incorporated into a checklist. Asking questions regardless of condition is probably more workable for outcome measures than for specifications for care. Consider the specification that requires daily doses of insulin for insulin-dependent diabetics. A question on missed doses of insulin would not appear to be sensible to a patient who is not a diabetic and who is not taking insulin. Respondents may in fact become irritated and break off the interview if asked a number of questions that do not appear to be sensible.

Of course, the strategy of asking more questions regardless of condition will increase the length of the interviews, particularly the two-week sample member interview. Table V.9 presents information on the length of the interviews in the pilot study. With its extensive use of skip logic based on

TABLE V.9

INTERVIEW LENGTH
(Minutes)

Interview	Median	Mean	Standard Deviation	Range
Screening Interviews				
Sample member	11	11.5	4.9	6-36
Caregiver	2	2.3	1.7	**1-18**
Two-Week Interviews				
Sample member	29	29.7	11.3	4-72
Caregiver	4	3.9	2.5	1-14
Six-Week Interview	7.3	14.2	6.1	3-36

NOTE: These interview lengths entail estimates of the time that interviewers were on the telephone conducting a completed interview. The times are calculated automatically from the time that the computer file was opened for that case until the interviewer logged off the case. If he or she did not log off immediately after completing the interview, the calculated times would be incorrect. For example, this could happen if the interviewer went to lunch and left the case "up." Because extreme outliers probably represent a failure to log off immediately, we have excluded extreme outliers from these statistics. In addition, if the delay was lengthy (e.g., overnight), the computer automatically entered an error code. We have excluded cases with such error codes.

condition, the two-week interview required an average of about 30 minutes to complete. The addition of a few questions on the two-week interview would not pose a problem: however, if many questions were added, it would probably be important to delete other questions to keep the length of this interview manageable. There are some descriptive questions in the two-week interview which contain information that is necessary for the application of the guidelines and which might be eliminated or moved to the six-week interview. For example, the detailed measures of functioning might be greatly streamlined and some questions on functioning eliminated.

Greater Use of Callbacks. Another strategy for reducing missing data would be to use callback interviews to obtain data that were skipped due to inconsistencies. In the pilot study, callbacks were used to obtain data which were missing because a condition or procedure listed in the medical record abstraction form had not been known at the time of screening. (This would have been the case either if ICD-9-CM codes had not been available at the time of screening or if additional ICD-9-CM codes had been added after the time of screening **and** that condition or procedure had not been reported in the sample member screening interview.) The callback procedure could be extended to identify all inconsistencies between the medical records and interview data, and to generate callbacks for patients with missing data due to any such inconsistencies. This would require extensive additions to the code that generates callbacks.

Relying on callbacks would have two disadvantages. First, callbacks are expensive and impose greater burden on respondents. Second, the recall period would be quite lengthy for information obtained in callbacks. Even under the

best of circumstances, medical records abstraction forms would not be available for processing for quite some time after the patient had been discharged, and callbacks could not be made until the medical records abstraction forms were completed and processed. A lengthy recall period would probably not be a serious problem for some data elements. For example, respondents would be likely to remember the nature of problems leading to an unexpected readmission to the hospital. However, **it** would be a serious problem for many data elements. For example, it seems highly unlikely that respondents would be able to recall accurately whether the patient missed meals in the two weeks after discharge because he or she had no help with meal preparation.

Perhaps the best alternative is a combination of the various strategies, adding more questions on the two-week interview as a fall-back when data are missing from the records, asking more questions in the two-week interview regardless of condition, and using callbacks to resolve inconsistencies and collect missing data elements.

5. Revisions to the Medical Records Abstraction and Automated Procedures

In a separate report, **Markson** et al. (1989) reported that the clinical reviewers believed that the guidelines were not applied correctly in a number of the cases under their review. The authors present a detailed discussion of ten cases in which the clinical reviewers felt that, in their judgment, conditions that were found to be applicable under the automated procedures were not applicable, and conditions not found to be applicable **were** applicable. Overall, with respect to semi/unskilled guidelines, there were **41** cases in which the clinical reviewers felt that the guidelines that were

applicable had not been applied and 13 in which they felt that guidelines had been applied inappropriately. With respect to skilled care guidelines, there were 33 cases in which the clinical reviewers felt that an applicable guideline (or subdivision of an applicable guideline) had not been applied, and 33 cases in which they felt that a guideline (or a subdivision of a guideline) had been applied inappropriately. Many of the cases for skilled care involved situations in which one guideline (or one subdivision of a guideline) was applied and the clinical reviewers felt that a related guideline or another subdivision of the same guideline should have been applied. These cases were counted both as a case in which an applicable guideline had not been applied and as a case in which a guideline had been applied inappropriately.

Fortunately, for two reasons, the cases in which the clinical reviewers felt that the guidelines were applied inappropriately do not have a major impact on the analysis conducted in the pilot study. First, slightly less than half of the cases involved semi/unskilled care, and the argument for the validity of the semi/unskilled guidelines rests more on face validity than on empirical analyses. Second, the additions to and deletions of the applicable guidelines that were suggested by the clinical reviewers had little effect on whether care met the guideline specifications in a given case, because patients in the sample tended to experience either a very low level of care (which did not meet either the original set of guidelines or the revised set) or a relatively high level of care (which met both sets of guidelines).

Nevertheless, the results of the clinical review of applicable guidelines suggest that a number of refinements be made to the medical records

abstraction procedures and the automated procedures for applying the guidelines.

The discussion in **Markson** et al. indicates that five factors were involved in these ten in-depth cases:

o The clinical reviewers used the interview data to apply-the guidelines (rather than the medical records data) if the data conflicted and they believed that the interview data were more accurate. (This occurred primarily for the semi/unskilled guidelines on functioning.)

o The clinical reviewers and the medical records abstractor (who was also a clinician) reached different conclusions about ambiguous data.

o The clinical reviewers reached a different conclusion about ambiguous cases than the decision embodied in the automated procedures.

o The abstractor missed difficult-to-locate information.

o There was an error in coding, transcription, or data entry.

a. Inconsistencies in Interview and Medical Records Data

The medical records data and the interview data were inconsistent in a number of cases. Many, but not all, of these cases involved measures of functioning.

Functioning. The inconsistencies that involved functioning occurred for every functional activity, but **were** most prevalent for mobility and transfer.

The inconsistencies appear to have had multiple causes. Some of these inconsistencies can be explained by the fact that the interview data applied to a different time period and to a different setting than did the medical records data. The interview items asked about functioning on the first full

day at home,[13] while the medical records data items were intended to collect information on functioning in the hospital on the day of discharge (primarily via a review of nursing notes). Other inconsistencies were due to the difficulty of abstracting information on functioning from the medical record. The notations about functioning were often ambiguous, or no notations were made about functioning immediately prior to discharge. In the latter case, the procedures called for reviewing the nursing notes for the day before discharge and looking for indications that the patient had become independent prior to that time, so that it was reasonable to assume that he or she was still independent.

The procedures used to identify impairments under the automated process and under the clinical review differed. The clinical reviewers identified impairments in functioning on a case-by-case basis, while the automated process followed general rules. The clinical reviewers had access to the entire medical record and to the interview data on functioning. If the two data sources were inconsistent, the clinical reviewers would arrive at a judgment about the patient's functioning based on evaluating all of the information from both sources. In contrast, in the automated process, it was not possible to use one data source to evaluate the accuracy of the other. In particular, the computer algorithms embodied the assumption that the medical records data were preferable to the interview data and always used the former if they **were** available. Information might have been unavailable from

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[13]The interview items on functioning were designed to refer to the first full day at home because the guidelines are intended to cover post-hospital care. The level of inconsistency between the medical records and the interview items was not foreseen.

the medical record because it was missing in a particular case or because information on a particular activity was not abstracted from the record. Information on bathing, mobility, toileting, transfer, and eating was abstracted from the medical record, with the exception that information on whether a patient was **bedbound** was taken from the **interview.**[14] Interview data were used to measure functioning on the remaining activities for which **semi/** unskilled guidelines were developed (dressing, taking medication, meal preparation, and summoning assistance).

While a case-by-case review may be the most accurate way to determine functioning, it is obviously not feasible for a national survey. Rather, we must use the results of the case-by-case review to improve the automated procedures. Two basic alternatives are open to us: retaining the medical records as the preferred data source, or relying on the interviews as the preferred data source. Because information on some types of functioning is not available from the medical record and because the information that is available is sometimes ambiguous, interview data must be retained as a backup source if medical records are retained as the preferred data source. If medical records are retained as the preferred data source, the procedures for medical records abstraction must be refined and the interview items on functioning revised. One possible refinement to the abstraction process would

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[14]The availability of data on various activities was evaluated in the design phase of the pilot study. Data on these tasks were available for 90 percent of the records or more.

Interview data on bedboundness was used because it was not possible to use the medical records to determine accurately the amount of human assistance required for those who received assistance with transfer. If the patient must be lifted, he or she is bedbound.

be to collect information on bedboundness from the medical record whenever it is available. The rules on the treatment of ambiguous data should also be clarified. While the abstractor was instructed to code ambiguous cases as missing, more specific procedures could probably be developed by reviewing all the cases in which the clinical reviewers felt that the guidelines were not applied correctly. Revising the interview items would entail **making** them refer to functioning on the last day in the hospital so that they would refer to the same time period and setting as do the medical records.

The two basic alternatives for measuring functioning have different advantages and disadvantages. The major advantage of abstracting information on functioning from the medical records is that recall is not an issue, and the information would not be affected by the measurement error associated with recall. On the other hand, there are several disadvantages to using the medical record as a source of information on functioning:

o The information in the medical record refers to the period prior to discharge and to functioning in a hospital setting, while the guidelines focus on functioning at home after discharge. For some types of patients (e.g., dementia patients), **functioning** will be affected by the environment, and, of course, the functioning of patients who are recovering from an acute illness can change over the period of a couple of days.

o Information on functioning is not consistently available from medical records for all the activities of interest.

o The information on functioning in the medical record is sometimes ambiguous and is thus prone to measurement error.

Based on a review of the advantages and disadvantages of the two approaches and on our experience with using the first alternative in the pilot study, our recommendation is that a national study should rely on interview

data as the preferred source of data on functioning. This recommendation is predicated on administering the interview data as quickly as possible after the two-week post-discharge period so as to keep the recall period short. Given that discharge from the hospital is a salient event, measurement error associated with recall seems unlikely to present a serious problem, if the recall period is short (as it was in the pilot study).[15]

Inconsistencies Involving Medical Condition. Two of the ten cases that were reviewed in depth because the clinical reviewers did not feel that the guidelines had been applied correctly involved inconsistencies in medical condition information from the interview and the abstraction form. Both of these cases involved reports of the use of aerosol medications. In one case, the patient reported using such medications at discharge, but no such medications were listed in the medical record. Because it seems likely that a patient would not report using aerosol medications if he or she was taking them, we recommend that information which indicates that such medications are used be accepted from either the interview or the medical record.

b. Interpreting Ambiguous Cases

Some of the cases in which the clinical reviewers believed that the guidelines were not applied correctly involved ambiguous situations in which the interpretations of the evidence by clinical reviewers and the medical record abstractor differed. For example, one such case involved a patient

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[15]Data were also collected in the pilot study interview on functioning on the last day in the hospital. The intent was to assess the extent of measurement error by comparing these data with the comparable data on functioning abstracted from the medical records. This comparison was never conducted. However, the fact that the information on functioning in the medical records data was often ambiguous suggests that this comparison would not have been definitive.

with heart failure and shock who also had a decubitus ulcer at admission. The ulcer was noted as one of the patient's problems in the admission statement. The issue is whether the ulcer should have been interpreted as a <u>reason for</u> admission so that the guideline on the management of existing incontinence would have been applicable. Another case involved a patient who suffered new stress incontinence while coughing the night before discharge, but was voiding without stress incontinence on the day of discharge. The issue is whether this patient was incontinent at discharge under the guidelines.

Procedures must be developed to enable the abstractor to proceed appropriately in ambiguous situations. For the first example given above, the procedure might call for treating a decubitus ulcer as the reason for admission only if it was listed as the principal diagnosis. Only the most serious case **of** mismanagement of incontinence would be included under this procedure; some cases in which existing incontinence was not being managed properly would surely be ignored. However, using principal diagnosis would ensure that the need for care would not be overstated under the guidelines. In the second example given above, the procedure might be to treat the patient as incontinent at discharge if he or she was incontinent during the 24 hours prior to discharge. The argument for this interpretation is that a professional visit is required if a substantial likelihood exists that incontinence had not resolved by discharge. **A** review of all the cases in which the clinical reviewers and the automated process identified different guidelines as applicable would be useful in identifying other ambiguous situations for which specific procedures could be developed.

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c. Ambiguous Cases: Clinical Reviewers and the Automated Procedures

Some of the cases in which the clinical reviewers believed that the guidelines were not applied correctly appear to have involved ambiguous situations in which the logic embodied in the automated procedures differed from the logic used by the clinical reviewers.[16] One example of such a case involved a patient with chronic pulmonary edema. While the clinical reviewers believed that the guideline on cardiopulmonary monitoring was applicable, the logic underlying the automated procedure is that only acute pulmonary edema is serious enough for this guideline to be applicable .[17]   A second example involved a patient with an order for aerosol therapy. The issue is whether or not the treatment was new; the guideline on aerosol therapy is applicable only to new treatments.   Under the automated procedures, information on the prior use of aerosol medication is collected only in the interview. (This decision was made because we believed that this information would not consistently be available from the medical records.)   In this case, the patient did not report the prior use of aerosol medication, but such use was clearly documented in the medical record.   This case suggests that the automated procedures for aerosol therapy should be revised so that information on prior use can be collected from the medical record and from the interview, and that an indication of prior use be accepted from either source. A review of all the cases in which the clinical reviewers and the automated process

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[16]For this report, it was not possible to trace cases through the algorithms.

"However, if the patient had a diagnosis of congestive heart failure (which could have led to chronic pulmonary edema) and had two previous hospital admissions in the previous six months, this guideline would have been applicable under the automated procedures.

identified different guidelines as applicable would be useful in identifying other ambiguous situations in which a revision of the automated procedures may be required.

d. Difficult-to-Locate Information

In order to minimize the cost of medical records abstraction as much as possible in preparation for a national study, the procedures for abstracting medical records in the pilot study were designed to focus on the parts of the record in which the requisite information was most likely to be located. The abstractor was referred to different parts of the record for different information. For example, she was referred to the nursing notes, nursing care plan, or discharge plan for information on instruction during the hospital stay, and to laboratory reports for information on the blood sugar levels of diabetic patients.

Some of the cases in which the clinical reviewers believed that the guidelines were not applied correctly appear to have involved cases in which the abstractor overlooked information.[18] For example, one such case involved a newly diagnosed insulin-dependent diabetic. The issue is whether or not the patient was instructed in administering insulin in the hospital. This patient received instruction relatively early in the stay, and it appears possible that the abstractor overlooked it.

The failure to locate information in the record was probably due partially to the time devoted to abstracting each record. A goal of 30

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[18]It has not been possible to fully investigate alternative explanations for the differences between the clinical reviewers and the automated procedures with respect to applicable guidelines.

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minutes per case was set for the abstraction process; the average time actually spent was 18 minutes per record (see Table **V.10**).[19] We recommend that the instructions to the **abstractors** be revised to deemphasize the time required to abstract each record.

However, it does not seem necessary to require that the abstractor review the entire record for each case. Rather, we recommend that the abstractor be directed to read all of certain parts of the record for patients with certain types of conditions. For example, the abstractor would be directed to read any physical therapy notes for patients with an impairment in mobility or transfer . **The** notes would then be a source of information on the receipt of physical therapy and on the receipt of instruction during the **stay.**[20]

We also recommend revising the rules on preferences for medical records or interview data for difficult-to-locate items so that we accept either the medical records or the interview data unless there is reason to believe that the respondent will not be able to provide accurate information for a particular issue. Instruction in the hospital is one type of **difficult-to-**locate information for **which** we recommend that either data source be accepted. For example, we would treat an insulin-dependent diabetic as having received instruction in the hospital in administering insulin injections if the patient or caregiver reported receiving such instruction in the interview or if evidence of such instruction were abstracted from the medical record.

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[19]**This** figure does not include time for obtaining the file. This time cannot be disaggregated from the time for sample intake, which averaged 17 minutes per case, including travel time.

[20]**It** would also be a source of information on functioning in the hospital if that information is abstracted **from** the medical record.

TABLE **V.10**

TIME REQUIRED TO COMPLETE MEDICAL
RECORDS **ABSTRACTION** FORM

Statistic	Minutes
Mean	18.11
Median	17.00
Standard Deviation	10.03
Range	3 - 78 minutes

e. Transcription and Data Entry Errors

Finally, some of the cases in which the clinical reviewers believed that the guidelines were applied incorrectly appear to have involved transcription or data entry errors of information collected in the medical records abstraction form. A few errors of this type are inevitable, and only a few were uncovered in the clinical review.

It is not clear that additional quality control procedures would reduce the number of such errors sufficiently to warrant their cost. Independent checks were used at key points in the transcription and data entry process of medical records abstraction in the pilot study. All of the data elements in the medical records abstraction form were data-entered twice, and any inconsistencies were resolved by referring to the hard copy. In addition, the ICD-9-CM codes (for which transcription errors are likely) were collected at the time of sample intake, printed out for the abstractor, and checked at the time of medical records abstraction. These checks did not include a systematic review of the ICD-9-CM codes assigned by hospital staff, although our staff did correct several errors in the ICD-9-CM codes assigned by hospital staff . (These errors were noted in the course of completing the abstracting form.) While hospital coding errors are likely, independent coding of -medical condition would be quite expensive and is probably unwarranted.

VI.   CONCLUSIONS AND RECOMMENDATIONS

The purpose of the pilot study was to develop, test, and suggest refinements to a methodology for measuring the adequacy of post-hospital community care among Medicare patients and the adverse outcomes associated with inadequate care.   -

Three major components of this overall methodology were to be tested:

o The validity of the guidelines in defining levels of care that are minimally adequate to prevent adverse outcomes

o The effectiveness of screening procedures **at** identifying patients who needed post-hospital care and of the procedures for classifying them by the risk of experiencing inadequate care and suffering adverse outcomes

o The feasibility of the strategy for collecting the data necessary for screening and risk classification purposes and to apply the guidelines

Because the guidelines are central to this methodology, the most important of these three issues is the validity of the guidelines.   The capacity of the methodology to identify instances in which care is inadequate depends critically on having valid definitions of minimally adequate care which may be compared with services actually received.   The purpose of the screening and **risk** classification procedures is to identify patients who need care as defined **by** the guidelines and who are at risk of experiencing inadequate care and suffering adverse outcomes as defined by the guidelines. The function of the data collection strategy is simply to implement the application of the guidelines and the screening and risk classification procedures.

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Beyond testing the validity of the guidelines, the effectiveness of the screening and risk classification procedures, and the feasibility of the data collection strategy, the pilot study entailed suggesting refinements to each component to improve its performance in a national study.

In this chapter, we:

o Summarize the evidence supporting the validity of the guidelines

o Present our recommendations for refining the guidelines

o Summarize our conclusions about the effectiveness of the screening and risk classification procedures and our recommendations for their revision

o Summarize our conclusions about the feasibility of the data collection strategy

o Suggest refinements to that strategy

A. GUIDELINES

The evidence presented in this report and in the separate report on the clinical review (Markson et al., 1989) indicates that the guidelines have both face-validity and construct-validity.   The body of the empirical evidence indicates that, taken as a group, the guidelines, do provide a reasonable definition of minimally adequate care, However, the evidence also suggests that the guidelines require some refinement.

1. Validity

In this section, we review the evidence on the validity of the guidelines.

a. <u>Face-Validity</u>

The face-validity of the guidelines is a function of the process through which the guidelines were developed and refined. The guidelines were developed by experienced clinicians in conjunction with a distinguished panel of experts who offered extensive clinical experience in the provision of **post-**hospital community care. The guidelines were refined on the basis of the results of a pretest in which the care needs of **50** patients were reviewed by clinicians and compared with the care prescribed under the guidelines. Finally, the hospital records of 100 pilot study patients **were** reviewed by clinicians at Boston University, and the care needs of these patients were compared with the guideline prescriptions. The clinicians concluded that the guidelines are generally clinically sound. (The results of this review are summarized below.)

b. <u>Empirical Tests of the Validity of the Guidelines</u>

Three distinct empirical approaches were used to analyze the validity of the guidelines:

o A comparison of orders for post-hospital care (abstracted from hospital records) with the types and amounts of care called for in the guidelines

o A comparison of the likelihood of adverse outcomes when **care** needs under the guidelines were met and when they **were** not met

o The clinical review of hospital medical records for a sample of cases to assess whether the guidelines defined minimally adequate care for those patients

The results of each generally support the validity of the guidelines as a group.

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<u>Comparison of Orders and the Guidelines</u>. We hypothesized that, if the guidelines (as a group) provided a valid specification of minimally adequate care and were applicable (as intended) to the great majority **of** patients who required post-hospital care, most patients whose hospital records contained orders for post-hospital care would also have such care specified under the guidelines, and the amounts of care ordered for these patients would be no smaller than the amount called for under the guidelines. Because we could not differentiate cases in which no care was ordered from cases in which care was ordered but information on orders was missing from the hospital records, we excluded from this analysis all patients for whom the hospital records contained no information on orders for post-hospital care. In addition, because the guidelines for semi/unskilled care do not specify minimally adequate care in terms of the amount of formal care, we did not consider orders for home health aides or homemakers in this analysis.

Most of the 299 patients in the sample for whom it was possible to apply the guidelines had orders for either nursing care, therapy, or physician care in the two weeks following discharge. Seventy-five had orders for nursing or therapy, and 200 had orders for follow-up physician care. The comparison of care ordered with the care prescribed under the guidelines was conducted separately **for these** two groups of patients.

The results of this comparison support the validity of the guideline specifications of minimally adequate care. The guidelines prescribed skilled care for 89 percent of the patients with orders for nursing or therapy and for 80 percent of the patients with orders for physician care. For the cases in

which information on the amount of care ordered was available, the amount ordered was never smaller than the amount prescribed under the guidelines.

Comoarison of the Likelihood of Adverse Outcomes. As indicated above, the guidelines are designed to specify the types and amount of care that are minimally adequate to prevent adverse outcomes. We hypothesized that if, as a group, the guidelines provided a valid definition of minimally adequate care, adverse outcomes would be substantially more likely when care met the guidelines than when it did not.

To test this hypothesis, we relied on the individual guideline rather than the patient as the unit of analysis. Using the patient as the unit of analysis could have overstated the effect on adverse outcomes of the failure to experience the types and amounts of care called for under the guidelines, due to the fact that multiple guidelines may apply to an individual patient, and a patient could fail to receive the care called for under one guideline and suffer an adverse outcome related to another guideline. In this circumstance, the failure to receive the care prescribed under the guidelines could apparently cause an adverse outcome when it actually did not.

Because we wished to assess the validity of the guidelines as a group, we examined the distribution of the pilot study data. We determined that the scope of the guidelines is generally represented in the pilot study data. Although a marked concentration of observations exists for the Medication Supervision Guideline, no marked concentration of observations exists in which care did not meet the guidelines or in which adverse outcomes were suffered.

Using the individual guideline as the unit of analysis, we estimated the likelihood of an adverse outcome when the care experienced met the guidelines

and when it did not, controlling for the characteristics of the patient at the time of hospital discharge. After deleting some adverse outcomes for which the measures proved to be problematic, we estimated that adverse outcomes were about twice as likely when the guidelines for skilled care were not met, over four times as likely when the guidelines for semi/unskilled care were not met, and almost three times as likely when the guidelines for all care were not met (relative to the likelihood of adverse outcomes when the guidelines are met). The differences for skilled care and for all care are statistically significant. Those for semi/unskilled care (for which the sample of observations that failed to meet the guidelines is very small) approach statistical significance.

To further test whether the guidelines specified minimally adequate care, we varied the guideline specifications. (All of the variants involved only the guidelines for skilled care.)

One variant encompassed the guidelines for which the clinical panel had the most difficulty in reaching consensus. Generally, this variant entailed revising sixteen guidelines to make them applicable to fewer patients, reducing the specified number of professional visits, or specifying a later initial visit (relative to discharge). When we relaxed the guideline specifications in this **manner,** the number of cases in which care did not meet the guidelines declined. However, the sample size declined as well, primarily because the specifications of the guideline on medication supervision had been revised to make it applicable to far fewer patients. In addition, other guidelines that called for one professional visit during the two weeks after discharge were not applicable when specifications on the number of **profession-**

als were relaxed (to "zero" visits). The estimates based on this relaxed specifications and reduced sample are not statistically significant: however, their direction indicates that adverse outcomes are <u>less</u> likely **when** care does not meet the guidelines than when it does. This result suggests that this relaxed variant of the guidelines does not provide a better specification of minimally adequate care.

We also developed variants of the guidelines in which we (1) uniformly <u>relaxed</u> the specifications on the number and timing of the initial visit for all guidelines (by specifying one less visit and a later initial visit); and (2) uniformly <u>tightened</u> the specifications on the number and timing of the initial visit for all guidelines (by specifying one more visit and an earlier initial visit). The estimates for the uniformly relaxed variant are similar to those for the variant discussed above for which we relaxed selected guidelines: these estimates indicate that adverse outcomes are less likely when care does not meet the guidelines than when it does.   Uniformly tightening the guideline specifications also generated estimates which indicated that adverse outcomes are less likely when care does not meet the guidelines.

Overall, the results obtained when we relaxed or tightened the guideline specifications are less reasonable that those obtained with the original guideline specifications (developed in conjunction with the **clinical** panel). These results are encouraging in **that** they suggest that the original guideline specifications are neither too relaxed nor too tight. However, an analysis of the results of the selectively relaxed and uniformly relaxed guidelines indicated that the specifications for the Medication Supervision Guideline are

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quite important to the significant results obtained for the original guidelines. Due to the substantial proportion of observations that involved the Medication Supervision Guideline, revisions to the specifications of this guideline can dramatically change the estimates of the effect of experiencing care that does not meet the guidelines. Fortunately, the results of the clinical review of records did not indicate that revisions were required to the specifications of the Medication Supervision Guideline.

We also varied the guideline assumptions which involved the types of care for which a follow-up visit to a physician is be counted toward meeting the specifications on the number of professional visits. To test these assumptions we identified eight guidelines (e.g., diabetic care and wound care), for which it was reasonable to assume that physicians would personally provide care under some circumstances. When follow-up physician visits are counted for these additional guidelines, we estimate that adverse outcomes are about 2.4 times as likely when care does not meet the guidelines as when it does (compared with an estimate of 2.06 times as likely when follow-up physician visits are not counted). These estimates suggest that follow-up physician visits should be counted for additional guidelines.

Clinical Review of Records. The purpose of the clinical review of 100 records was twofold: (1) to identify the types of cases for which the guidelines required refinement; and (2) to address whether the guideline specifications represented minimally adequate care and the extent to which it was reasonable to assume that observed adverse outcomes were associated with experiencing care that did not meet the guidelines. The clinical review focused on the skilled care guidelines.

Because the primary purpose of the clinical records review was to refine the guidelines, we selected a judgmental rather than a random subsample of records for review. The subsample included cases that represented all the guidelines which were not met (in one or more cases), regardless of whether adverse outcomes were suffered. It also included cases to which the application **of** guideline specifications would most likely be problematic (specifically, all patients whose care met the guidelines but **who** nevertheless suffered adverse outcomes, and complex cases involving comorbidities).

Two clinicians (a nurse and a physician), both of whom experienced in the provision of home care to the elderly, reviewed the hospital medical record for the entire hospital stay for each patient in the subsample. In each case, the clinicians reached independent judgments about the types and amounts of care that were minimally adequate to prevent adverse outcomes. These judgments covered the number and timing of professional visits for the skilled care guidelines, as well as other specifications for both skilled and semi/unskilled care (e.g., help with eating twice a day, and daily insulin injections). These clinical judgments were then compared with the types and amounts of- care specified by the guidelines for each of the patients in the subsample. The clinical judgments about minimally adequate care were identical to the guideline specifications on the number of professional visits and on the timing of those visits for 68 and 71 of the 100 cases reviewed, respectively. The cases in which the clinicians and the guidelines did not agree are about equally split between cases in which the clinicians judged that the care specified by the guidelines was less than minimally adequate and those in which they judged that it was more than minimally adequate.

Considering that the cases for the clinical review sample were deliberately selected to include the cases to which the application of the guideline specifications would most likely be problematic (and hence would need refinement), this level of agreement provides evidence that the guidelines are generally clinically sound.

Moreover, a review of the cases in which the guidelines and clinicians did not agree suggests that some of the cases of disagreement involved differences about the procedures for implementing the guidelines rather than the guidelines themselves.

2.   Refinements to the Guidelines

The various analyses of the pilot study suggest a number of refinements to the guidelines. Refining individual guidelines was the primary purpose of the clinical review of hospital records'conducted by Boston University, and the refinements suggested by that review are discussed in detail in a separate report (Markson et al., 1989). Refining the guidelines was also the primary purpose of the clinical review of the medical records abstract forms for cases in which the post-hospital care that was ordered differed from the care prescribed under the guidelines. In addition, some refinements to individual guidelines were suggested by the review of cases that suffered adverse outcomes which was conducted in conjunction with an analysis of the likelihood of adverse outcomes.

In the discussion that follows, we first discuss our recommendation on the addition of unexpected death as an adverse outcome. We then consider each guideline individually, describing the revisions (if any) recommended for each.

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a. Un<u>expected</u> <u>Death as an Adverse Outcome</u>

We recommend that unexpected death caused by life-threatening complications or an exacerbation of an original, life-threatening condition be included as an adverse outcome for a number of guidelines. Table VI.1 lists the guidelines for which we recommend that unexpected death be added as an adverse outcome, as well as the life-threatening complications or conditions associated with each guideline.

We recommend that the approach adopted for measuring death as an adverse outcome be similar to the approach adopted for hospital readmission and emergency room and physician visits. Unscheduled hospital readmissions and unexpected emergency room and physician visits which involve complications of a condition or procedure or for an exacerbation of the original condition are currently included as adverse outcomes for many guidelines. We recommend that whether death was unexpected and the. cause of death be ascertained from family members, who would be serving as proxy respondents for deceased sample members for the two-week interview. Because such questions are sensitive and must be worded carefully, their number would be very limited. They would include one question on whether the patient's death had been unexpected and one question on the cause of death. The responses to the question on the cause of death would be compared with a list of the patient's conditions and the **life-**threatening complications associated with each to determine whether death might reasonably be attributed to these conditions.

b. <u>Guideline-by-Guideline Discussion of Recommendations</u>

In the discussionwhich follows, guideline numbers appear in parentheses. While we have developed a considerable amount of empirical evidence in the

TABLE VI.1

GUIDELINES FOR WHICH UNEXPECTED DEATH IS RECOMMENDED
AS AN ADVERSE OUTCOME

Guideline (Number)	Life-Threatening **Complication** or Condition
Help with Eating (2)	Dehydration, malnutrition
Help with Medicines (5)	Medication incident, exacerbation of condition for which medication was being taken
Help with Meal Preparation (9)	Dehydration, malnutrition
Diabetic Care **(10A-10C)**	Hyperglycemia, hypoglycemia, coma
Chest Physical Therapy **(13A-13B)**	Lung infection and congestion, difficulty breathing, pneumonia
Oxygen Therapy (14)	Shortness of breath, lung or heart disease
Aerosol Therapy **(15A-15B)**	Shortness of breath, difficulty breathing, chronic obstructive lung disease
Tracheostomy Care (16)	Atelectasis, plugged trachea, pneumonia
Monitoring Cardiopulmonary Status (17)	Shortness of breath, lung or heart disease
Venipuncture for Blood **Drawing** (18)	Complication related to reason for blood test order (e.g., hyperglycemia if tests for blood sugar ordered)
Coumadin Monitoring (19)	Recurrent thrombosis or embolism, bleeding
Medication Supervision **(20A-**20B)	Medication incident, exacerbation of condition for which medication was to be taken
Intravenous Therapy, via Peripheral Line **(21A-21B,** 22)	Phlebitis, recurrent or resistant systemic infection, adverse drug reaction, medication incident
Intravenous Therapy, via Central Line (23)	Medication incident, separation of the line with extensive bleeding
Enteral Feeding, Nasogastric (24)	Dehydration, intractable diarrhea, pneumonia

TABLE VI.1 (continued)

Guideline (Number)	Life-Threatening **Complication or** Condition
Enteral Feeding, Gastrostomy (25)	Dehydration, intractable diarrhea, pneumonia
Dysphagia (26)	Dehydration, pneumonia
Care of **Bedbound** Patients (34)	Dehydration, pneumonia
Care of Comatose Patients **(35A-35B)**	Pneumonia, trauma, dehydration
Mobility Therapy for the Chairbound **(36A-36B)**	Dehydration
Muscle Strengthening, Flexibility, and Tone Management Exercises Following Hip Surgery (38, 39, 40)	Phlebitis
Pain Management **(41A-41B)**	Medication incident
Psychiatric Monitoring (43)	Medication incident, dehydration
Follow-Up of the Cognitively Impaired (44)	Dehydration, trauma
Follow-Up Professional Monitoring **(45A-45B)**	Complication of cardiothoracic, major abdominal, or pelvic surgery: exacerbation of original condition

pilot study to support the validity of the guidelines, their face-validity is also extremely important. As indicated earlier, the face-validity is based on the fact that the guidelines represent the consensus of a clinical panel, drawn from several different disciplines and from different parts **of** the country. The importance of face-validity is particularly clear when one considers **that** much of the empirical evidence pertains to the guidelines taken as a group. Due to the importance of face-validity, we believe that refinements to the guidelines that affect the specifications of minimally adequate care should be put before a clinical consensus panel. Several of the refinements recommended below involve such refinements. Therefore, we urge that the government convene a clinical consensus panel to consider them. In addition, such a panel may wish to consider the need for additional guidelines to cover old conditions that are not being treated properly.

Help Summoning Assistance **(1)**. Because we have not developed measures of adverse outcomes for summoning assistance and because the guidelines are defined in terms of the care necessary for preventing adverse outcomes, we recommend that the guideline on summoning assistance be deleted.

'We considered adopting unexpected death and unscheduled service use **(e.g.,** hospital readmission) as adverse outcomes for this guideline, but rejected doing so for two reasons. First, the approach for ascertaining the cause of death and service use described above would be unlikely to uncover instances in which an inability to summon assistance in a timely manner contributed to unexpected death or service use. Rather, identifying whether an inability to **summon** assistance contributed to unexpected death or unscheduled service use would require developing a special series of

questions. Second, even with a special series of questions, it would probably be very difficult to attribute unexpected death or unscheduled service use accurately to an inability to summon assistance. In discussing unexpected death or unscheduled service use with patients and caregivers, physicians would be likely to attribute death or unexpected service use to medical conditions or complications. They would be much less likely to discuss the role of the inability to summon assistance in a timely manner. Thus, patient and caregiver reports on inability to summon assistance as a cause of death or service use would be likely to rely heavily on lay perceptions, uninformed by discussion with a physician.

Nonetheless, we recognize that summoning assistance is a very important issue. Accordingly, we recommend that questions on the ability to summon assistance and on any perceived consequences of the inability to summon assistance (in cases in which that occurs) be included in a national study.

Help with Eating (2). We recommend that unexpected death be added as an adverse outcome for the guideline on help with eating. (See Table VI.l.)

Help with Transfer **(3).** Some morbidity outcomes that are included for guidelines for related conditions (for example, mobility therapy for the **chairbound) were** inadvertently omitted from the current guideline on help with transfer. The omitted morbidities include skin breakdown, new contractures, new decubitus, and impaction. We recommend that these morbidities be added as adverse outcomes for the guideline on help with **transfer.**[1]

'These morbidities were included as adverse outcomes for help with transfer in the analysis of the validity of the guidelines discussed in Chapter III of this report.

Help with Dressing (4).   We recommend that the guideline on help with dressing be deleted.   We have been unable to identify any adverse outcomes that affect patient health and that are measurably more likely if the specifications of the guideline for help with dressing are not met. However, because having fresh clothing is important to the quality of the patient's life, we recommend that questions on the frequency with which clothing is changed be included in the national survey interview and be asked of patients who need assistance with dressing.

Help with Medicines (5).   We recommend that unexpected death be added as an adverse outcome for the guideline on help with medicines. (See Table VI.l.)

Help with Walking (6).   Some morbidity outcomes were inadvertently omitted from the current guideline on help with walking.   These include skin breakdown and new contractures.   We recommend that these morbidities be added as adverse outcomes.*

In addition, we recommend that a single fall be considered an adverse outcome for the guideline on help with walking.   Currently, only multiple falls are considered an adverse outcome for this guideline: however, a single fall is treated as an adverse outcome for related guidelines (for example, the guideline on help with transfer).

Because repeated falling is an important issue, we recommend that a question be included in a national survey to ascertain the approximate number of falls in the two weeks following discharge.   Such a question would facilitate estimating the incidence of repeated falls. Currently, the two-

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[2]These morbidities were included as adverse outcomes for help with transfer in the analysis of the validity of the guidelines discussed in Chapter III of this report.

week interview question on multiple falls is asked only of those who need assistance with walking.

Help with Bathing (7). We recommend that the guideline on help with bathing be deleted. We have been unable to identify any adverse health outcomes that are measurably more likely if the specifications of the guideline for help with bathing are not met. However, because bathing periodically is important to the quality of the patient's life, we recommend that questions on the frequency of bathing be included in a national survey and be asked of patients who need assistance with bathing.

Help with Toileting (8). Currently, the specifications for minimally adequate care for toileting consider only accidents due to the necessity of waiting for help. However, accidents reflect only one aspect of inadequate help with toileting, and several of the adverse outcomes listed for the guideline on help with toileting (fall, impaction, and urinary tract infection) do not involve accidents. We recommend that a specification that help with toileting be provided as necessary be added. The guidelines for transfer and walking currently specify minimally adequate care in this manner.

Help with Meal Preparation (9). We recommend that unexpected death be added as an adverse outcome for the guideline on help with meal preparation. (See Table VI.l.)

Diabetic Care **(10A-10C).** We recommend that a clinical consensus panel reconsider the timing of the initial visit for insulin-dependent diabetics who have no caregiver and who are newly diagnosed or who have entered the hospital because they cannot control diabetes. Currently, Guideline **10A** applies to insulin-dependent diabetics who enter the hospital because they lack control

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or who are newly diagnosed and instructed in the hospital. This guideline specifies that the initial visit be no later than the third day after discharge. However, an initial visit on the day after discharge may be required for some patients to verify their ability to self-administer insulin. Our specific recommendation is that insulin-dependent diabetics who enter the hospital because they cannot control diabetes and have no caregivers should be seen no later than the day after discharge. The panel may also want to consider changing the specification for the timing of the initial visit for newly diagnosed insulin-dependent diabetics who were instructed in the hospital and have no caregivers, particularly for such patients who report that they have been unable to administer their own insulin at discharge. We do **not** propose that the specified number of professional visits be revised for guideline **10A.**

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table **VI.1.)**

Amnutation Care and **Preprosthetic** Training **(11A-11B).** We recommend that the direct measures of pain be deleted from this guideline and from the two otherguidelines to which they apply (IV-therapy for pain medication and pain management). These direct measures are reports of pain that has prevented sleep and of pain that has prevented activities of daily living. Our hope was that the direct measures of pain would capture <u>severe</u> pain; however, the results from the pilot study suggest that they appear to capture **discomfort** as well. The other direct measures of pain that we reviewed in developing the pilot study instrumentation are quite lengthy, and we cannot recommend their use in a national survey. Rather, we recommend that severe pain be measured

through unscheduled hospital readmission and unexpected emergency room and physician visits due to pain.

<u>Eve Care **(12A-12B)**.</u> No revisions are recommended.

<u>Chest **Physical Therapy (13A-13B)**.</u> We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Oxvnen Theraov **(14)**.</u> We **recommend** that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Aerosol **Therapy (15A-15B)**.</u>

We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Tracheostomv Care (16)</u>. We recommend that unexpected death be-added as an adverse outcome. (See Table VI.l.)

<u>Monitoring Cardiooulmonarv Status **(17)**.</u> We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Veniouncture for Blood Drawing (18).</u> We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Coumadin Monitoring (19)</u>. We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Medication Suoervision **(20A-20B)**.</u> We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

<u>Intravenous Antibiotic Theraov, via **Peripheral** Line **(21A)**.</u> We recommend that a consensus panel reconsider the number of visits for intravenous antibiotic therapy (guideline **21A)** required in the home and in ambulatory care facilities. We do not believe that six visits is sufficient in a home setting, although this number may be sufficient in an ambulatory setting. We

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recommend that the panel consider subdividing this guideline by setting and specifying a minimum of ten visits for Guideline 21A in the home setting.

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Intravenous Chemotherapy. via Peripheral Line (21B). We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Intravenous Pain Medication. via Peripheral Line (22). For the reasons discussed in conjunction with the guideline on amputation care and preprosthetic training, we recommend that adverse outcomes on the inability to sleep and to perform activities of daily living due to pain be deleted.

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Intravenous Therapy, via Central Venous Line (23). We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Enteral Feeding. via Nasonastric Tube (24). We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Enteral Feeding. via Gastrostomy (25). We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Dysphagia (26). Pneumonia was inadvertently omitted as an adverse outcome. We recommend its inclusion.

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Urinary Incontinence Management (27A1-27A3,27B). We recommend that unplanned nursing home admission due to the fatigue of caregivers be added as an adverse outcome for patients who require urinary incontinence management.

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Such nursing home admission is currently an adverse outcome for patients who are comatose or **bedbound** or who suffer from cognitive impairment or bowel incontinence.

Intermittent Catheterization **(27B)**. No revisions are **recommended.**

Care of Urinary **Catheter/Nephrostomy** Tube **(28A-28B, 29A-29B, 30A-30B)**. No revisions are recommended.

Bowel Incontinence Management (31). No revisions are recommended.

Ostomy Care **(32).** We recommend that a consensus panel consider subdividing this guideline on the basis of (1) whether or not instruction was received in the hospital: and (2) whether the patient or caregiver was able independently to care for the ostomy upon discharge. While it seems. unlikely that a patient with a new colostomy, ileostomy, or urinary diversion would be discharged without instruction, any patients who were should be seen on the same day that they are discharged. We do not recommend that the specified number of professional visits for patients who received no instruction in the hospital be revised. Some patients receive excellent instruction in the hospital and are able to care for their ostomy independently at the time of discharge. Such patients do not require as much care as is currently specified under this guideline. Rather, we recommend a total of two visits--the first by the third day after discharge--for patients who prior to discharge have demonstrated independence in caring for the ostomy.

Wound Care **(33A-33N).** We recommend that the size of surgical wounds be ignored in the guidelines for wound care and that the number of visits and the timing of the initial visit currently specified for small surgical wounds of the trunk (i.e., those smaller than half-dollar size) be adopted for all

surgical wounds regardless of size.   While the size of other types of wounds (e.g., a decubitus ulcer) may effect the amount of care required to some degree, the size of surgical wounds has little or no effect on care requirements.

We recommend that surgical wounds of the head, neck, and legs that are draining or infected be added to the current wound care guideline on surgical wounds of the upper extremities.   By adopting this recommendation, the guidelines would specify one professional visit in the two weeks after discharge for patients with such wounds, with the initial visit no later than the fifth day after discharge.   Wounds located in these areas are not covered under the current guidelines.   We also recommend that all types of wounds, other than **surgical** wounds, be included in the guidelines that currently cover ulcers, burns, and gangrene.

Bedbound Patients **(34).**   Pneumonia and dehydration were not included as morbidity adverse outcomes.   We recommend their inclusion.

We recommend that unexpected death be added as an adverse outcome.   (See Table VI.l.)

Comatose Patients **(35A-35B).** Pneumonia and dehydration were not included as morbidity adverse outcomes.   We recommend their inclusion.

We **recommend** that unexpected death be added as an adverse outcome.   (See Table VI.l.)

Mobility Therapy for the Chairbound **(36A-36B).**   We recommend that the title **of** this guideline be changed from mobility therapy for the chairbound to mobility therapy for impaired transfer.   The current title is misleading,

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because patients who are impaired in transfer, but who are not chairbound, are included.

We recommend that the requirement that a caregiver be available for all patients be dropped from Guideline 36A (the availability of a caregiver is currently included in the description of the condition), and that the guideline be subdivided on the basis of the presence of an able caregiver. Some patients who are impaired in transfer are appropriately discharged to the community without a caregiver. [3] We recommend that the current care specifications (three visits, the first by the third day after discharge) be retained for such patients. In contrast , patients who are impaired in transfer and who have an able caregiver require less care than currently specified: we recommend that a total of two visits be specified, the first by the fifth day after discharge. In addition, we recommend that further information be collected to ascertain more effectively the caregiver's ability to help with transfer and mobility. Caregivers who are themselves frail cannot provide such assistance.

We also recommend that Guideline 36B (for patients who are impaired in transfer and who received physical therapy in the hospital) be subdivided on the basis of whether the patient was bed or chairbound at discharge. For patients who are bed or chairbound, we recommend that the number of visits specified be increased to two (one visit is currently specified in the two weeks following discharge). A minimum of two visits are required to perform a home evaluation, to continue the transfer training begun in the hospital,

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[3] Patients who are bedbound require a caregiver; however, the guideline on the care of the newly bedbound, which does specify that a live-in caregiver be available, will apply to such patients.

and to provide teaching to the caregiver. We do not recommend any change in the specified timing for the initial visit.

Skin breakdown and dehydration were inadvertently omitted as adverse outcomes for the current guideline on mobility therapy for the **chairbound.**[4] We recommend their inclusion.

Finally, we recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Mobility Therauv for **Impaired** Ambulation (37). We recommend that the current guideline on mobility therapy for impaired ambulation be subdivided to separate patients who received physical therapy in the hospital from those who did not. (The guideline for mobility therapy for the chairbound is currently subdivided in this manner.) We recommend that the specified number of professional visits be reduced **to** one for patients who received physical therapy in the hospital. We do not recommend that the specified timing of the initial visit be changed even if physical therapy was received in the hospital. With the recommended changes, Guideline 36 and Guideline 37 would specify comparable amounts of care (one visit, the first by the third day after-discharge) for patients who are impaired in transfer (but who are not bed or chajrbound) and in mobility and who received physical therapy in the hospital.

The current guideline on mobility impairment applies only **to** patients who are newly impaired in mobility. We recommend that a consensus panel consider creating a subdivision of this guideline to apply to patients with-existing

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[4]**These** morbidities were included as adverse outcomes for help with transfer in the analysis of the validity of the guidelines discussed in Chapter III of this report.

mobility impairment who have a recent history of falls (e.g., three falls in the two weeks preceding the hospital stay). For patients with such a history, we recommend that the guidelines specify one professional visit during the two weeks after discharge. The purpose of this visit would be to assess the functioning of the patient in the home situation.

Some morbidity outcomes were inadvertently omitted from the current guideline on mobility therapy for impaired ambulation. These include fall, skin breakdown, contracturea, and new decubitus . We **recommend** that these morbidities be added as adverse **outcomes.**[5]

Muscle Strengthening. **Flexibility,** and Tone Management Exercises (38-40). We recommend that unexpected death be added as an adverse outcome. (See Table **VI.1.)**

Pain Management **(41A-41B).** For the reasons discussed in conjunction with the guideline on amputation care and preprosthetic training, we recommend that the adverse outcomes on the inability to sleep and to perform activities of daily living due to pain be deleted.

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table **VI.1.)**

Cast Care- **(42).** No revisions are recommended.

Psychiatric Monitoring (43). We recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Follow-Up of the **Cognitively** Impaired (44). The current guideline on follow-up of the cognitively impaired does not include patients' who are

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'These morbidities were included as adverse outcomes for help with transfer in the analysis of the validity of the guidelines discussed in Chapter III of this report.

delirious at discharge. In developing the current guideline, we **assumed** that patients with unresolved delirium were not discharged. However, this assumption does not appear to be warranted; such cases were included in the clinical review sample. If left untreated, delirium carries a high risk of morbidity (particularly dehydration and falls and other injuries) and may even lead to mortality. Therefore, we recommend that a subdivision be added to Guideline 44 to make it applicable to patients with delirium at discharge. Patients to whom this subdivision applied would be identified by marked reductions in alertness and orientation between admission and discharge, or by a notation in the hospital record that the patient was delirious in the **24-** hour period before discharge. Further, we **recommend** that the guideline on delirium be subdivided on the basis of the presence of a live-in **caregiver.** For patients who have a live-in caregiver available, we recommend two professional visits, the first no later than the third day after discharge: for patients without a live-in caregiver, we recommend four professional visits in the two weeks following discharge, with the initial visit no later than the day after discharge.

We also recommend that patients with **Alzheimer's** disease and other dementia be_ added to the portion of the guideline on the follow-up of the cognitively impaired. Currently, the guideline applies to patients with a live-in caregiver **only** if there is a change in the primary caregiver or in the residence. We recommend that patients with live-in caregivers also be included in this guideline if the functional status of a patient changes markedly. A marked change in functional status would be defined as a change from independence to dependence (that is, from requiring no human assistance

to requiring such assistance) in a personal care task, taking medications, or meal preparation.

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table VI.l.)

Follow-up Professional Monitoring (45A-45B). We recommend that the guideline on follow-up professional monitoring be applied to patients who have a history of severe functional impairment. There were a number of such patients for whom no current skilled guideline was applicable, but for whom the hospital records contained orders for a follow-up physician visit in the two weeks after discharge. We recommend that such severely impaired patients be defined as those who were impaired at admission in eating or in transfer and in a total of four of five personal care activities (bathing, dressing, toileting, transfer, and eating). Impairment would be defined as needing human assistance to complete a task. For such severely impaired patients, we recommend that the guideline specify one professional visit in the two weeks following discharge.

We also recommend that the guideline on follow-up professional monitoring be applied to patients who were admitted for trauma to the head or neck which caused contusions of the brain or spinal cord and had hospital stays of two days or longer. (Here, length of stay would exclude patients who were hospitalized briefly for observation.) For such patients, we recommend that the guideline specify one professional visit in the two weeks following discharge. .

In addition, we recommend that unexpected death be added as an adverse outcome. (See Table IV.1.)

B. THE SCREENING AND RISK CLASSIFICATION PROCEDURES

In this'section, we summarize our conclusions and present recommended refinements for the screening and risk classification procedures, in turn.

1. Screening Procedures

Given the broad scope of the care covered, it is not surprising that the great majority of Medicare patients discharged from the hospital need either skilled or semi/unskilled care under the guidelines. About 84 percent of the patients for whom screening was completed were identified as needing skilled care (and possibly semi/unskilled care as well) and another 10 percent were identified as needing semi/unskilled care only. Only about 6 percent were identified as needing no care. A comparison of care needs according to the screen with care needs according to the guidelines confirms that the screening procedures are generally correct in terms of the need for care prescribed under the guidelines, and thus that most Medicare patients need some type of care under the guidelines when discharged from the hospital.

Despite the overall accuracy of the screening procedures for those **identified** as needing care, some of the cases identified as **not** needing care according to the screening procedures needed care according to the guidelines and were incorrectly screened out. While these "false negative" cases comprised a relatively large portion of the patients screened out (62 percent), they represented only 6 percent of the patients who needed care under the guidelines. A review of the guidelines applicable to the false negative cases suggests that the incidence of such cases could **be** greatly reduced by adding questions on the receipt of laboratory tests and follow-up physician visits and specific personal care activities to the screening

interview.   (Many personal care activities were not differentiated in the screening interview.)

The fact that the vast majority of Medicare patients discharged from the hospital to the community need skilled or semi/unskilled care under the guidelines calls into question the utility of the screening process.   Might it be more cost-effective to eliminate screening (as a method for identifying patients who need care) and to collect the full data set (i.e., two-week and six-week interviews and medical records abstract forms) for all eligible patients discharged from the hospital7 Assuming that the risk classification procedures are to be retained, it is probably not cost-effective to eliminate the screening process, even though only a small proportion of patients are screened out as not needing care.   We reached this conclusion because the abstraction of ICD-O-CM codes and the collection of interview data (which are used in screening) are also necessary to implement the risk classification procedures.   Eliminating screening on the need for care would permit eliminating only some questions on the screening interviews, which would not generate sufficient savings to offset the substantial cost of collecting the full data set for patients who do not need care. Given the likelihood that revising the screening procedures would substantially reduce the proportion of patients incorrectly screened out (perhaps to 3 percent of those who need care), the expense of collecting the full data set on the entire population would not seem warranted.

2. Risk Classification Procedures

The ultimate purpose of classifying patients by the risk of experiencing care that does not meet the guidelines and of suffering adverse outcomes is

to obtain a sufficient sample of patients who actually experience such care and actually suffer such outcomes to support analyses that link inadequate care to adverse outcomes. The risk classification procedures fulfilled this purpose. They differentiated patients who experienced care that did not meet the guidelines **and** who suffered adverse outcomes from those for whom both conditions did not hold. When the two aspects of risk are considered separately, patients in the high-risk group were not much more likely to experience care that did not meet the guidelines than were those in the **low-**risk group in the pilot study sample: however, they were much more likely to suffer adverse outcomes. Moreover, the evidence suggests that we would have found a larger (and statistically significant) difference in the incidence of care that did not meet the guidelines for the high- and low-groups had the final risk classification procedures been in place at the beginning of fielding . (The risk classification procedures were revised during fielding.)

C. DATA COLLECTION STRATEGY

The experience in the pilot study indicates that the data collection strategy is feasible and deals successfully with a number of potential problems. However, major revisions are necessary to reduce the proportion of observations that are lost to analysis due to missing data. Refinements are necessary for clarifying the procedures for medical records abstraction and the automated procedures for applying the guidelines.

The methodology does deal successfully with a number of issues that we were very concerned about as we began the pilot study. The cooperation of hospitals was satisfactory. Over 80 percent of the hospitals that were approached agreed to cooperate. However. **private for-profit hospitals were**

the most reluctant to participate, suggesting that the non-participating hospitals in a national study might differ systematically from participating hospitals. Patients and their caregivers were willing to participate despite the fact that the patients had recently been discharged from the hospital; the completion rates for the interviews ranged from 88 to 99 percent. Selecting the sample of discharged patients, obtaining ICD-9-CM codes, and processing this information in a timely way did not present intractable problems; we were able to identify eligible patients and obtain ICD-O-CM codes for almost 90 percent of sampled patients in time to begin screening interviews on schedule. Information on functioning was available from the medical record for the vast majority of patients.

Using hospital discharge disposition codes to identify patients discharged to the community was a minor problem. We failed to identify a small minority of eligible patients who were coded as discharged to an institution but who were actually discharged to the community.

The procedures for medical records abstraction and the automated procedures for applying the guidelines require refinement. Resolving inconsistencies in the information on functioning in the medical records data and interview data is a major issue. The clinicians who participated in the clinical review of records identified a number of cases in which they felt that the guidelines were not applied correctly. A review of these records indicates that five factors were involved in these cases:

o A coding, transcription, or data entry error occurred.

o The clinical reviewer missed difficult-to-locate information.

o The clinical reviewers and the medical records abstractor (who was also a clinician) reached different conclusions about ambiguous cases.

o The clinical reviewers reached a conclusion about ambiguous cases that differed from the decision embodied in the automated procedures for application of the guidelines.

o The clinical reviewers used the interview data to apply the guidelines (rather than the medical records data) if the data from the two sources were inconsistent, and they believed that the interview data were more accurate.

Coding, transcription, and data entry errors seem to have been a relatively minor problem. It is probably not cost-effective to introduce additional procedures to reduce them further. It should be possible to reduce the problems associated with the second, third, and fourth factors by (1) increasing the time devoted to medical records abstraction from an average of 20 to 30 or more minutes per record; (2) clarifying the abstraction procedures to be followed in ambiguous situations: and (3) revising the automated procedures (including the computer algorithms) as appropriate. Several refinements to the medical records abstraction process and to the automated procedures for applying the guidelines can be identified based on the ten cases reviewed in depth by the clinical reviewers. We recommend that all the cases in which the clinical reviewers felt that the guidelines had not been correctly applied be reviewed, which should allow us to identify other refinements.

The extent of inconsistencies between the medical records and interview data suggest that a substantial revision is necessary to resolve this issue. For data on functioning, we recommend that the interviews be selected as the preferred data sources, and that information on functioning not be abstracted

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from medical records. Because the inconsistencies that involved medical condition seem to be caused primarily by poor documentation in the medical record, we recommend that information on the receipt of instruction and on certain types of treatments be accepted from either the interviews or the medical records.

Finally, the greatest problem with the data collection strategy of the pilot study is the extent of missing data. Due to missing data on condition, the adequacy of care, or outcomes, somewhere between 23 and 37 percent of the actual observations on individual guidelines were lost to the analysis. The data collection strategy for the pilot study assumed that the major source of missing data would be a lack of information on the condition of the patient in the hospital records. To meet this potential problem, we included questions in the interviews as backup sources of information. What this strategy overlooked was the effect of inconsistency between the medical records and interview data. Such inconsistency is a major source of missing data. Because abstracting information from the full medical record is a very time-consuming process and because medical records are not available for abstraction until some time after the patient has been discharged, the interview skip-logic relied on information on the patient's condition reported in the interviews. When the patient report was in error (based on information obtained later from the medical record), using the condition-specific skip logic led to missing data.

A massive amount of data are required to apply the guidelines and to determine the adequacy of care and the presence of adverse outcomes. While one cannot hope to eliminate missing data entirely, it is important that it

be reduced substantially. Two revisions to the data collection strategy would help resolve inconsistencies between the interviews and medical records: (1) changing the skip logic of the interviews so that questions are asked regardless of condition, to the extent that doing so is feasible; and (2) expanding the callback process so that patients are recontacted to resolve any inconsistencies between the hospital records and the interview data and to provide any missing data. An analysis to determine whether cases with missing data differ systematically should probably also be considered for a national study .

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APPENDIX A:

GUIDELINES FOR CARE

TABLE A.1

SEMI/UNSKILLED GUIDELINES

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care		Adverse Outcomes
			Frequency	Other	
1	Unable to summon help without human assistance	Help with summoning assistance		Someone available to place calls or emergency response system	
2	Unable to eat without human assistance	Help with eating	2 times a day		Unscheduled hospital readmission, emergency room, or physician visit for dehydration or malnutrition
3	Unable to transfer to and from bed or chair without human assistance	Help with bed/chair transfer	As needed		Unscheduled hospital readmission, emergency roan, or physician visit for fall, new decubitus. or new onset of urinary incontinence Fall New onset of urinary incontinence
4	Unable to dress for day or change night clothes without human assistance	Help with dressing	1 time a day		
5	Unable to take own medications without human assistance	Help with medicines		No missed doses of medication due to lack of help	Unscheduled hospital readmission, emergency room, or physician visit for medication incident or exacerbation of condition for which medication was to be taken

TABLE A.1 (continued)

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care Frequency	Specifications for Minimally Adequate Care Other	Adverse Outcomes
6	Unable to walk without human assistance	Help with walking	As needed		Unscheduled hospital readmission. emergency room or physician visit for problem associated with impaired mobility (including falls and new decubitus) Skin breakdown Falls (3 or more in 2 weeks) New decubitus
7	Unable to manage full bath without human assistance	Help with bathing	1 full bath a week		
8	Unable to use toilet, bedpan, or bedside commode for either bladder or bowel functions without human assistance	Help with toileting		No more than one accident due to having to wait for help	Unscheduled hospital readmission, emergency room, or physician visit for new onset of incontinence, skin breakdown, impaction, urinary tract infection, or fall New onset of urinary incontinence Fall Skin breakdown Impaction Urinary tract infection

A.2

TABLE A. 1 (continued)

Number	Condition/Type of Patient	Type of C&e	Specifications for Minimally Adequate Care Frequency	Other	Adverse Outcomes
9	Unable to prepare meal withuut human assistance	Help with meal preparation	1 full meal a day, 1 light meal and 1 snack daily	If therapeutic diet is ordered, doesn't fail to follow it because of lack of help	Unscheduled hospital readmission, emergency room or physician visit for dehydration or malnutrition

TABLE A.2

SKILLED CARE GUIDELINES

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
10A	Insulin Dependent Diabetes: Newly diagnosed AND Instructed In hospital OR Entered hospital for lack of control of diabetes OR Hypoglycemia In hospital OR Blood sugar over 500 In hospital	**Diabetic Care** Medication monitoring, diabetic teaching, venipuncture or fingerstick, footcare	By third day after discharge	3	Daily Insulin Injection	Unscheduled hospital readmission, emergency room visit, or physician visit related to diabetes (Including infections, coma, hyperglycemia, and hypoglycemia) Nypoglycamia Nyperglycamia
10B	Patient or caregiver responsible for administering insulin cannot do so (e.g., stroke, marked visual impairment, or newly legally blind) or new (ID) diabetic and no teaching of insulin Injection In hospital	As above, plus insulin Injection	Day after discharge	4	Daily Insulin injection Blood sugar test In first 2 weeks	As above
10C	Non-Insulin Dependent Diabetes: Newly diagnosed OR Hypersmolar coma OR Blood sugar over 500 In hospital	**Diabetic Care** Medication monitoring, diabetic teaching, venipuncture or fingerstick, footcare	Within first week			Unscheduled hospital readmission, emergency room visit, or physician visit related to diabetes (including infections, coma, hyperglycemia, and hypoglycemia) Hypoglycemia Hyperglycemia

TABLE A.2 (continued)

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
11A	Discharged with new amputation or stag revision, mid-foot or higher AND Has live-in caregiver (does not laclude patients with amputation of digits of band, with pylon, or with hip disarticulation)	Amputation Care and Preprostbetic Training Including nursing and physical therapy	Day after discbarge	4		Unscheduled hospital readmission, emargency room visit, or physician visit related to amputation (Including Infection, reopening of Inclsion, skin breakdown, pain, contractures, falls, and deprersion) Depression Unable to sleep due to pain Unable to perform ADLs due to pain
11B	As above, but no live-in caregiver		Day after discbarge	6		As above
12A	Any lens procedures AND Patient or caragiver unable to administer medication	Eye Care	Day after discbarge	1	Medication as prescribed	Unscheduled bospital readmission, emargency room visit, or physician visit related to eyes (Including infection) Infection
12B	Any lens procedures MD Patient or caregiver able to administer medication		By tblrd day after dlrcbarge	1	Medication as prescribed	As above
13A	Pulmonary disease AND New order for chest physical therapy AND No instructed caregiver (Including nacaragiver) OR Old order and no caregiver	Chest Physical Therapy Instruction In postural dralnage, percussion, bnatblng and endurance exercises	Day after dltcbarge	5		Unscheduled hospital readmission, emergency roam visit, or physician visit related to pulmonary disease (Including lung Infection and congestion, new pneumonia. and difficulty breatblng) New pneumonia
13B	New order with instructed caregiver		By tblrd day after discharge	2		As above
14	New order for oxygen at home	Oxygen Therapy lank, concentrator, or liquid cylinder	For equipment, day of discharge or day prlor to discharge By third day after discharge for professional	2	24 hour on-call availability for equipment	Unscheduled hospital readmission, emargency room visit, or physician visit related to oxygen use or lung or heart disease (including shortness of breath, mental status changes, and hypotension)

A.6

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
15A	Chronic obstructive lung disease AND New order for aerosol medication using equipment (oxygen or compresser)	Aerosol Therapy	For equipment, day of discharge or day prior to discharge Day after discharge for professional	2	M-hour on call availability for equipment	Unscheduled hospital readmission, emergency room visit, or physician visit related to chronic obstructive lung disease (Including shortness of breath and difficulty breathing)
159	As above and aerosol using hand-bald inhaler (no equipment)		Day after discharge	2		As above
16	Patient discharged with new tracheostomy AND Has caregiver with som Instruction	Tracheostomy Cam	For equipment, day of discharge or day prior to discharge gay after discharge for professional	4	24-hour on-call availability for equipment	Unscheduled hospital readmission, emergency room visit, or physician visit related to tracheostomy (Including atelectasis, plugged trachea, and pneumonia) Pneumnla
17	New myocardial infarction OR Diagnosis of unstable angina or hypertensive crisis or malignant hypertension or pulmonary edema OR Diagnosis of chronic obstructive luag disease or congestive heart failure and 2 previous hospital admissions In tba last 6 months	Monitoring cardiopulmonary status (physician or nurse)	Within first week			Unscheduled hospital readmission, emergency room visit. or physician visit for original condltion, Intractable paln, or shortness of breath
18	Blood test ordered at discharge to take place within first two weeks	Venipuncture for blood drawing (physician, nurse or lab)	By third day after discharge	2	Patient was told not to take any other medications, Including over-the-counter medications, without chacking with doctor Any test ordered was done, unless order was cancelled	Unscheduled hospital readmission, emergency room visit, or physician visit for bleeding, recurrent thrombosis, or embolism
19	Patient discharged with new coumadin order (including new dosage of old order)	Draw blood for protime (physician, nurse, or lab)	gy third day after discharge	2	Patient was told not to take any other medi-cations, Including over-the-counter mdicatlons, without checking with doctor Any test ordered was done. unless order was cancellad	Unscheduled hospital readmission, emergency room visit, or physician visit for blaedlng, recurrent thrombosis, or embolism

TABLE A.2 (continued)

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number o Visit (First 3 Weeks)	Other	
20A	Multiple prescription medications: 4 or mre, any one of which Is new orchanged AND Patient and caregiver not Independent	Medication Supervision · Administration, super- vlslon, and monitoring, including topical medi- cations, supposltorles, eye drops, injections, and excluding vitamins (physician or nurse)	By third day after discharge	2		Unscheduled bospltel readmission, emergency room visit, or physician visit related to improper or Inadquate administration of medicines
20B	Multiple prescrlptlon medications: 5 medications, any one of which is new or changed, even if independent OR Medication Incident (e.g., dlgltoxlclty) as cause of admission, as indicated by ICD-9 code or statement In record that medication non-compliance resulted in the admissions		Within first week	1		As above
21A	Discharged with orders for IV antibiotics via peripheral line AND Available caregiver	IV Therapy via Peripheral Line Intravenous antibiotic therapy	Tla of first scheduled dose	6	24-hour on-call avallablllty Available caregiver If IV comes act, reinsert so that no more than 3 doses are missed	Unscheduled hospital readmission, emergency room vlslt. or physician visit for recurrent or resistant systemic lnfectlon, adverse drug reaction or problems related to IV (e.g., phlebltls, local Infection)
21B	Discharged with orders for IV chemotherapy vla peripheral line AND Available caregiver	IV Therapy via Peripheral Line Chemotherapy	Time of first scheduled dose	Every scheduled dose If heparin loch, ● ln- imum of 5	24-hour on-call availability	Unscheduled hospital readmission, emergency row visit, or physician vlslt for local toxic reaction to drug or problem related to IV (e.g., phlebltls, local lnfectlon)
22	Discharged with orders for IV pain medication	IV Therapy via Peripheral Line Pain mdlcatlon	Time of first scheduled dose	4 unless heparin loch, then 5	live-in caregiver 24-hour on-call availability	Unscheduled hospital readmission, emergency room visit, or physician visit, inadequate pain control, or pain medication overdose or problw related to IV (e.g.. phlebltls, local Infection) Unable to sleep due to pain Unable to perform ADLs due to pain

TABLE A.2 (continued)

Number	Condition/Type of Patient	Type of Care	Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	Adverse Outcomes
			Specifications for Minimally Adequate Care			
23	New orders for medication or PPN/TPN vla central line	IV Therapy vla Central Venous Line Ikdlcatlon or total or partial parenteral nutrition (TPN or PPN)	Day after discharge	6	Live-la caregiver Instruction begun in hospital 24-hour on-call avallablllty	Unscheduled hospital readmission, emergency ma visit, or physlclan visit ralated to central line or medication being glven (lncludlng lnfactlon or inflammatlon of the site and teparatloa of line wlth extenslve bleeding posslble)
24	Discharged with new nasogastric tuba **AND** Instruction glvan in hospital	Enteral feeding with nasogastric tuba	Day after discharge	3	If NG tube out, reinserted wlthln 12 hours If dlabetic and NG tube, blood sugar test wlthln 2 weeks	Unscheduled hospltal readmission, emergency room visit. or physlclan visit for dehydration or tuba-related problems (unless only for re-insertion), pneumonia, or dlarrbea Pneumonia Diarrhea (more than four days. 4 stools/day)
25	glschargad wltb new gastrostomy or jejunostomy feeding **AND** Instructloa given la bospltal	Enteral feeding with gastrostomy or jejunostomy	gay after dlscbarge	3		Unscheduled hospltal readmission, aaargency room visit, or physlclan vlslt for dehydratlon or tube-related problems (unless only for re-insertlon), dlarrhea, pneumonia, or lnfactlon of site Dlarrhea (more than four days, 4 stools/day) Pneumonia Infection of site
26	New onset of swallowing disorder without feeding tube	Dysphagia Evaluatlon and treatment program	Day alter discharge	2		Unscheduled hospltal readmission, emergency room vislt, or physlclan vlslt for aspiration, lnadquate intake, or dehydratlon Dehydratlon Pneumonla

A.8

TABLE A. 2 (continued)

Number	Condition/Type of Patient	Type of care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
27A-1	New urinary incontinence AND Immobility to tba extent tbat patient is unable ta ambulate without assistance AND Instructed in hospital	Urinary Incontinence Management	Within first week	1	Live-In caregiver	Unscheduled hospital readmission. emergency room visit, or physician visit for skin break-down, dermatitis, or new decubitus Skin breakdown New decubitus Dermatitis
27k2	As above, but not instructed in hospital		By third day after discharge	2	Live-in caregiver	As above
27A-3	Old urinary incontinence and unable to ambulate without assistance AND Admitted for skin breakdown or decubitus associated with incontinence		Within first weak	1	Live-in caregiver	As above
270	New order for Intermittent catheterization AND Instruction begun in hospital	Intermittent Catheterization	Day after discharge	2	Live-in caregiver	Unscheduled hospital readmission. emergency room visit, or physician visit for urinary retention or recurrent or worsened incontinence Recurrent urinary incontinence
28A	Discharged with new Folly or suprapubic catheter MU Patient or careplvw instructed in hospital	Care of Urinary Catheter	Within first week	1		Unscheduled hospital readmission, emergency room visit, or phy-slclaa visit related to catheter (unless visit only for replacement), Including Infection, bleeding, and skin breakdown
28B	As above, bat not instructed		By third day after discharge	2		As above
29A	Discharged with new condom catheter AND Patient or caregiver Instructad in hospital		By third day after discharge	1		A. 5 above plus penile edema
29B	As above, but not instructed		As above	2		As above

TABLE A.2 (continued)

Number	Condition/Type of Patient	Type of Care	Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	Adverse Outcomes
			Specifications for Minimally Adequate Care			
30A	Discharged with new nephrostomy tube AND Patient or caregiver instructed in hospital		By third day after discharge	2		Unscheduled hospital readmission, emergency mom visit, or physician visit related to nephrostomy tube (unless visit only for replacemt), including Infection. bleeding, and skin breakdown
30B	As above, but not instructed		As above	3		As above
31	New bowel incontinence AND Immobility (to the extent that patient is unable to ambulate without assistance) or cognitive impairment	Bowel Iacoatlnaace Management	By third day after discharge	2	Caregiver available	Unscheduled hospital readmission, emergency mom visit, or physician visit due to problems related to bowel Incontineuce (lacludlag sklnbreakdoun, dematltls, and urinary tract Infection) Skin breakdown Dermatitis Urinary tract infection Unplanned admission to nursing home from hom or after another bospttal staydueto caregiver fatigue
32	Discharged with new colostomy, ileostomy, or urinary dluersloa	Ostomy Care	Day after discharge			Unscheduled hospital readmisslon, emergency roam visit, or physician visit for problem with ostomy or bowel regulation, skin breakdown, or depression Skin breakdown Depression
33A	Discharged with post-surgical mound of upper extramltles which is draining or infected	Wound Care	By fifth day after discharge	1		Unscheduled bospltal readmission, emergency room vlslt, or physiclan vlslt related to wound, including Increased Infection or dralnage, increased size or depth of wound, incision breakdown. increased pain, or bleeding

A.11

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
33B	Discharged with post-surgical wound of trunk which is draining or infected and half-dollar size or smaller AND Patient has caregiver or can reach wound and is not bed- or chairbound AND Hospital instruction		By fifth day after discharge	2 or as ordered if less		As above
33C	As above, but no hospital instruction		By third day after discharge	2 or as ordered if less		As above
33D	Discharged with post-surgical wound of trunk which is draining or infected and half-dollar size or smaller AND Patient has no caregiver and cannot reach wound or is bed or chairbound	Wound Care	Day after discharge	5 or as ordered if less		As above
33E	Discharged with post-surgical wound of trunk which is draining or infected and larger than half-dollar size AND Patient has caregiver or can reach wound and is not bed or chairbound AND Hospital instruction		By third day after discharge	3 or as ordered if less		As above
33	As above, but no hospital instruction		Day after discharge	3 or as ordered if less		As above
33G	Discharged with post-surgical wound of trunk which is draining or infected and larger than half-dollar size AND Patient has no caregiver and cannot reach wound or is bed or chairbound	Wound Care	Day after discharge	6 or as ordered if less		As above

TABLE A.2 (continued)

Number	Condition/Type of Patient	Type of care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
33H	Discharged with draining or infected decubltus or burn or ulcer or gangrene of lower extremity, half-dollar size or smaller AND Patient bar a caregiver or can reach wound and is not bed or chairbound AND Instructed in bospital		By third day after discharge	2 or as ordered if less		As above
33I	As above, but aot lnstructad in hospital		Day after discharge	3 or as ordered if less		As above
33J	Discharged with draining or infected decubitus or burn or ulcer or gangrene of lower extremity half-dollar size or smaller AND Patient has no caregiver and cannot reach wound or is bed or chairbound	Wound Care	Day after discharge	5 or as ordered if less		As above
33K	Discharged wltb dralnlng or infected dacubltus or burn or ulcer or gangrene of lower extremity which Is larger than a half dollar AND Patient has a caregiver or caa reach wound and is aot bed or chairbound AND Instructed in hospital		By tblrd day after discharge	3 or as ordered if less		As above
33L ·	As above, but not Instructed in hospital	Wound Care	Day after discharge	3 or as ordered if lass		As above
33M	Discharged with dralnlng or Infected decubitus or bum or ulcer or gangrene of lower extremity which is larger than a half-dollar AND Patient has no caregiver and cannot reach wound or is bed or chairbound		Day after discharge	6 or as ordered if less		As above

TABLE A.2 (continued)

Number	Condition/Type Of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
33N	Discharged following amputation of great toe for gangrene and no caregiver		By third day after discharge	2 or as ordered if less		As above
34	Patient newly bedbound AND not comatose	Care of Bedbound Patients	By third day after discharge	3	Live-in caregiver	Unscheduled hospital readmission, emergency room visit, or physician visit for pneumonia, aspiration. Impaction, caregiver fatigue, decreased urinary output, new decubitus, contractures, or incontinence

New decubitus

New contractures

New urinary incontinence

Impaction

Unplanned admission to nursing home from or after another hospital stay due to caregiver fatigue |
| 35A | Patient discharged newly comatose | Care of Comatose Patients | By third day after discharge | 5 | Live-in caregiver | Unscheduled hospital readmission, emergency room visit, or physician visit for aspiration, pneumonia, Inadequate intake, decreased urinary output, new decubitus, non contractures, impaction, trauma to patient, or caregtver fatigue

New decubitus

Impaction

New contractures

Unplanned admission to nursing baa from home or after another hospital stay due to caregiver fatigue |
| 35B | Patient discharged with old coma | | Within first week | 1 | Live-in caregiver | As above |

A.14

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
36A	Discharged newly mobility impaired, unable to wlk, and assistance with transfer AND Caregiver • vailable AND No instruction	Mobility Therapy for the Chairbound Instruction In transferring, wheelchair use, and ambulation (PT and/or RN)	By third day after discharge	3		Unscheduled hospital readmission, emergency mu visit, or physician visit related to fall, skin breakdown, injury from wheelchair use, dehydration, impaction, orcoatrutares Fall New decubitus New contractures New onset of urinary incontinence Impaction Injuries from wheelchair use (cuts, bruises, scrapes)
36B	As above, but had physiul therapy instruction In bospltal		By third day after discharge	1		As above
37	New onset for patient not independent in ambulation (with or without aulstlve device--i.e., needs uslstuce te walk, to transfer independently or wltb assistance) AND Was uslsted to ambulate la hospital la lut24 boars of stay UNLESS Admitted for surgery unrelated to walking, and under 75 years old	Mobility Therapy for Impaired Ambulation Instruction In level ambulation and stair climbing wltb or without uslstlve device, such as cane, crutches, walker, pylu, brace. or prosthesis	By third day after discharge	3		Unscheduled hospital readmission, emergency roam visit, or physician visit related to fall, skin breakdown, or coatractares
38	Discharged independent in ambulation: 1. Following knee surgery	Muscle Strengthening, Flulbillty, and Tone Management Exercises	By third day after discharge	4		Unscheduled hospital readmission, emergency room visit, or un-scbedalad physician visit related to knee problem, fall, or contractares Fall New contractares

A.15

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number of Visits (First 3 Weeks)	Other	
39	2. Following blp surgery		By fifth day altar discharge	2		Unscheduled hospital readmission, emergency room visit, or physician vislt for blp problem, fall, coatractures. decubltus, or phlebitis Fall New coatractures New decubltus Phlebitis
40	3. With new fracture or paralyals of upper extremity with ADL impairment	Muscle Strengthening, Flexibility, and Tone Management Exercises	Within first week	2		Unscheduled hospital readmission, emergency room vislt. or physlclaa visit related to fracture or paralysis or injuries, including cuts, burns, or falls Fall
41A	Patluts discharged with malignant tumor, who received parenteral pain medication or oral opiates (except codeine and equivalents) in last 48 hours before discharge OR Patleats with any diagnosis who received 3 doses or opiates (greater than codeine) In the 48 hours prior to discharge	Pain Management Nursing, physical therapy, or physician care	By third day after discharge	2		Unscheduled hospital readmission, emergency room vislt, or physician visit for inadequate pain control or pain medication overdose Unable to sleep due to pain Unable to perform ADLs due to pain
41B	Patleats discharged with fractures who received parenteral or oral pain medications (greater than codeine) In last 48 hours before discharge		By tblrd day after discharge			As above
42	Presence of new shoulder or long leg cast on Presence of other type of new cast if transfer, bathing, or ambulation impaired	Cast can (physician or nurse)	Within two weeks			Unscheduled hospital readmission, emergency room visit, or physician visit related to cast (including swelling of limb below cast, skin breakdown. paln, and fall) Fall

Number	Condition/Type of Patient	Type of Care	Specifications for Minimally Adequate Care			Adverse Outcomes
			Timing of Initial Visit	Number o Visits (First 3 weeks)	Other	
43	Admitted for major (or psychotic) depression or suicide attempt	Psychiatric Monitoring Assessment and monitor-lo2 by any professional (i.e., physician, nurse, social worker, clinical psychologist)	Within two weeks	1	W-hour on-call availability	Unscheduled hospltel readmission, emergency room vlslt, or physician vlslt for depression or medication-related Incident, fall, urinary ntentlon, or dehy-dration Fall Urinary ntentlon
44	Discharged with diagnosis Of Alzheimer's disease or dementia or cognitive impairment AND Wandering, agitation, day/night reversal, or decreased eating AND No live-la caregiver or, if live-in caregiver, change in boa situation	Follow-Up of the Cognitively Impaired Professional to assess home and home situation	Within two weeks	1		Unscheduled hospital readmission, emergency room vlslt. or physician visit for trauma to patient, dehydration, or caregiver fatigue Unplanned admission to nursing home from home or after another hospital admission due to caregiver fatigue Getting lost outside the home
45A	Patient who had CABG or other cardiothoracic surgery OR Patients who had major abdominal or pelvic surgery and in hospital less than 4 days, or more than 2 weeks OR Any patient who had prostatectomy	Follow-Up Professional Monitoring (physician or nurse)	Within two weeks	1		Unscheduled hospital readmission, emergency nom vlslt, or physician vlslt for problem related to surgery or original condition
45B	Any patient in the hospital more than 3 weeks		Within two weeks	1		Unscheduled hospital readmission, emergency room vlslt, or physician vlslt nlatd to surgery or original condltlon

APPENDIX B:

TECHNICAL ISSUES

There are several technical issues that require more in-depth discussion than is provided in the body of this report:

o The derivation of the number of patients for whom we expect to observe multiple adverse outcomes if the observations are independent

o The rules for eliminating double-counting (that is, eliminating the repetition of non-unique outcome events)

o The overstatement and understatement associated with the rules on eliminating double-counting, the assumption that patients for whom we have no six-week interview data suffered no adverse outcomes, and the treatment of missing data

o The incidence of adverse outcomes when care met and did not meet the guidelines using the patient as- the unit of analysis, and the estimates of the **probit** coefficients using each applicable guideline as the unit of analysis

o The sample design

In this appendix, we discuss these issues in turn.

A. MULTIPLE OUTCOMES UNDER INDEPENDENCE

Even if the observations for the various guidelines applicable to a patient were independent, we would still expect to observe some patients with multiple adverse outcomes. Under independence, we would expect to be as likely to observe a second adverse outcome for a given patient as we would be to observe an adverse outcome for a different patient, and, similarly, for additional adverse outcomes beyond the second. (We refer here to unique, multiple adverse outcomes. Repetitions of the same outcome event are discussed in the following section.)

During weeks one through two, we observe a total of 65 unique, adverse outcomes in a total sample of 747 observations; thus, under independence, the probability that a given observation has an adverse outcome is 0.087 (65/747). If a patient has two guidelines applicable to him or her, the probability of observing two adverse outcomes under independence is the product of 0.087 with itself, or 0.00757. We can compute similar probabilities for observing two adverse outcomes during weeks one through two when three guidelines are applicable, for observing two adverse outcomes when four guidelines are applicable, and so on; and we can compute similar probabilities for observing three adverse outcomes when three guidelines are applicable, for observing three adverse outcomes when four guidelines are applicable, and so on. If we multiply each of the probabilities obtained from these calculations by the number of patients with the corresponding number of applicable guidelines, we obtain an estimate of the number of patients for whom we will observe unique, multiple adverse outcomes during weeks one through two under independence.

For weeks three through six, we repeat this process, using the proportion of adverse outcomes we observe for that period. We observe 21 unique adverse outcomes during weeks three through six in a sample of 678 observations: therefore, the proportion for weeks three through six is 0.031.

B. RULES FOR ELIMINATING DOUBLE-COUNTING

When the unit of analysis is each applicable guideline, it is possible for a single outcome event to be associated with more than one guideline. For example, consider a patient for whom the guideline on transfer and the guideline on mobility therapy for the chairbound are applicable. If this patient suffered a single fall, the adverse outcomes for **both** of these

B.2

guidelines would be set to one. However, the fall would actually represent a single outcome event. To treat it as an adverse outcome for both guidelines would be to double-count this event.

To prevent double-counting in such situations, we developed a set of rules to eliminate one of the repetitions of a single outcome event. The rules were as follows:

o If one repetition was associated with a guideline for which care did not meet the guideline specification, to retain the adverse outcome for that guideline and to delete the repetition for the guideline for which care met the guideline specification.

o If neither of the repetitions was associated with care that did not meet the guidelines or both were associated with such care, to select the guideline for which the repetition was to be deleted at random, using a random number table.

If a single outcome event was repeated for more than two applicable guidelines, we applied these rules serially to pairs of repetitions.

Based on these rules, 28 observations were deleted. Twenty of these observations involved the semi/unskilled guidelines on help with transfer (nine observations), walking (one observation), and toileting (ten observations). Eight involved the skilled guidelines for urinary incontinence management (one observation), ostomy care (one observation), care of_bedbound patients (one observation), mobility therapy for the chairbound (four observations), and pain management (one observation). Falls and impactions were the outcome events that were repeated most frequently.

The rules described above cover the elimination of repetitions when an adverse outcome occurs. Logically, there is also a corresponding issue of eliminating the double-counting of repetitions of the non-occurrence of an

adverse outcome. However, in this case, this issue is moot, because the dependent variable on adverse outcomes is an aggregate variable, and the aggregate variable for each guideline contains at least one outcome event that is unique to that guideline. (These unique outcomes involve the unexpected use of health services associated with inadequate care for that particular guideline.) The aggregate dependent variable will equal zero (i.e., no adverse outcomes) <u>only</u> if the unique adverse outcome equals zero. (Non-unique adverse outcomes must equal zero as well.) Thus, the dependent variable for the observations on two guidelines cannot take on the value of zero for both observations solely because repetitions of non-occurrence are double-counted.

Another approach to the problem of repetitions of adverse outcomes under the guidelines is to change the unit of analysis from each applicable guideline to each unique <u>outcome</u> for each patient. Under this approach, multiple guidelines involving different care could be associated with a given unique adverse outcome. It would therefore be possible to observe situations in which care met the specifications for one guideline associated with a unique adverse outcome and did not meet the specifications for another guideline also associated with that unique outcome. In such situations, it would seem reasonable to treat care as not meeting the guidelines associated with that adverse outcome. If this were done, the resulting data set would be identical to the one we obtained by using each applicable guideline as the unit of analysis and by applying the rules for eliminating double-counting discussed above. The difference in these two approaches is subtle and lies in the interpretation of the results. The present approach (using each applicable guideline as the unit of analysis) tends to ignore the totality of

care needs across guidelines, while an approach using each unique outcome for each patient as the unit of analysis would highlight the importance of the totality of care needs across guidelines.

C.   UNDER- AND OVERSTATEMENT

Several of the procedures that we used and the assumptions that we adopted had a tendency to bias our results in a positive or negative direction.   In this section, we discuss the under- and overstatement associated with three sources of bias: (1) rules for eliminating **double-**counting; (2) the inclusion of patients without six-week interview data: and (3) the treatment of missing data.

1.   <u>Rules to Eliminate Double-Counting.</u>

The effect of the rules on double-counting may be to overstate the number of instances in which care that does not meet the specifications for a given guideline is associated with an adverse outcome. Overstatement might occur because these rules stipulate that a repetition associated with care that did not meet the guidelines is retained over a repetition associated with care that met the guidelines.   On the other hand, rules stipulating that the repetition to be retained is to be selected randomly (without regard for the effect of the adequacy of care on adverse outcomes) would understate the number of instances in which care that did not meet the guideline led to an adverse outcome, since we do find that the adequacy of care has an impact on adverse outcomes.   In any event, any overstatement associated with the rules on eliminating double-counting is slight: there were only six sets of repetitions in which the outcome associated with inadequate care was retained

as a result of these rules.   If we assume the same relationship between adequacy of care and adverse outcomes that we observe overall, four of these six repeated adverse outcomes would be associated with care that did not meet the guidelines and two with care that met the guidelines.   If we randomly selected the guideline to be retained, we would expect to observe three observations in which care met the guidelines and three in which it did not. Thus, the probable effect of the rules on double-counting is to increase by one the number of observations with an adverse outcome when care did not meet the associated guideline (over what we would expect by chance) and, correspondingly,   to reduce by one the number of observations with adverse outcomes when care met the associated guideline.

2.   Patients without Six-Week Interview Data

The effect of our assumption that patients for whom we had no six-week interview data suffered no adverse outcomes is probably to understate the number of instances of adverse outcomes by two cases.   There are 70 guidelines applicable to the patients for whom we had no six-week data.   If we assume that they were as likely to suffer an adverse outcome as was the sample as a whole, we estimate that the number of instances of adverse outcomes is understated by two.

3.   Treatment of Missing Data

Some of the preliminary results discussed in Chapter V are presented with missing data excluded and with missing data included under the assumptions that care met the guidelines and that no adverse outcomes occurred. These two treatments of missing data may lead to, respectively, the overstatement and

understatement of the evidence of care that did not meet the **guidelines and** of adverse outcomes.

The Exclusion of Cases with **Missing** Data. Excluding cases with **missing** data would not bias the estimates if cases with missing data were similar to those' for which data were available with respect to the incidence of care that did not meet the guidelines and of adverse outcomes. However, there is reason to believe that the cases with missing data were _more_ likely to be cases in which care met the guidelines and no adverse outcomes occurred than cases in which care did not meet the guidelines and there were adverse outcomes. To the extent that this is the case, the exclusion of cases with missing data will overstate the incidence of care that did not meet the guidelines and overstate the incidence of adverse outcomes.

The expectation that cases with missing data are more likely to be cases in which care met the guidelines and no adverse outcomes were suffered flows from the fact that our measures of whether care met the guidelines and whether there were adverse outcomes were aggregate measures involving multiple care needs and multiple outcomes that were not independent of each other. **Non-**independence is an issue both when the unit of analysis is the patient and multiple guidelines may be applicable and when the unit of analysis is each applicable-guideline.

The aggregate variables on whether care met a given guideline and whether adverse outcomes were present for a given guideline were developed by scanning the data to identify **one** instance in which care did not meet the guidelines and **one** instance in which an adverse outcome was suffered. If such an instance was identified in the available data, the aggregate variable was

coded to indicate that care did not meet the guidelines or an adverse outcome was suffered, <u>regardless</u> of whether other data were missing. In contrast, if no such instance was identified but other data were missing, the aggregate variable was coded as missing because the missing data **might** have indicated that care did not meet the guidelines or that an adverse outcome was suffered. The aggregate variables for the different care specifications (e.g., the number of visits and the timing of the initial visit) and different adverse outcomes (e.g., morbidity and unexpected service use) for an individual guideline were developed in this way, as were the aggregate variibles for multiple guidelines applicable to the same patient.

Observations on different care specifications and different adverse outcomes are not independent within or across guidelines. Consider a patient to whom one guideline applied., If such patient received fewer visits than specified under a guideline, the first visit was also likely to be later than specified (relative to a patient whose care met the guidelines). If a patient had a morbidity outcome under a given guideline, he or she was also more likely to have an unexpected service use outcome (relative to a patient with no adverse outcomes). Nor are observations that are independent across multiple guidelines applicable to the same patient. Consider a patient to whom multiple skilled care guidelines applied. If such a patient had no visits from (to) a health care professional, his or her care would not meet the specifications of any of these **skilled** care guidelines. Finally, patients may suffer the same adverse outcome under multiple guidelines. (While repetitions of the same outcome event were deleted to prevent double-counting when each applicable guideline was the unit of analysis, double-counting was

not an issue when the patient was the unit of analysis and repetitions of the same outcome event were not deleted.)

The Inclusion of Cases with Missing Data.   Cases with missing data were included in some analyses under the assumptions that care met the guidelines and that no adverse outcomes occurred.   Because some of the cases with missing data probably did involve situations in which care did not meet the guidelines or an adverse outcome occurred, this treatment of missing data probably understates the incidence of care that did not meet the guidelines and the incidence of adverse outcomes.

D.   ADVERSE OUTCOMES WHEN CARE MET AND DID NOT MEET THE GUIDELINES

There are two issues involving the analysis of adverse outcomes when care met and did not meet the guidelines that require further discussion--the analysis of the incidence of adverse outcomes using the patient as the unit of analysis and the presentation of the estimates of the **probit** coefficients for the analysis, using each applicable guideline as the unit of **analysis.**

1.   Using the Patient as the Unit of **Analysis**

The analysis presented in Chapter III was designed to test the validity of the guidelines by examining whether adverse outcomes were more likely when care did not meet the guidelines than when it did. For such a test, it was important to keep the causal link between care and outcomes as **clearcut** as possible.   Because using the patient as the unit of analysis tends to blur this link, we used each applicable guideline as the unit of analysis in testing the validity of the guidelines.

Nevertheless, we did conduct some exploratory analysis using the patient as the unit of analysis. The results of this analysis were very different from the results on the likelihood of adverse outcomes using each applicable guideline as the unit of analysis. These differences led us to review crossover cases (that is, cases in which care did not meet one guideline and an adverse outcome was experienced on another guideline). Based on this review, we determined that the measures of adverse outcomes related to the Toileting Guideline were problematic and that the measure of pain was problematic. In this section, we present the exploratory results_ for the Basic Guidelines using the patient as the unit of analysis.

Table B.l indicates the percentages of patients in the pilot study suffering adverse outcomes when care met and did not meet the guidelines without controlling for patient characteristics. For skilled care, about 31 percent of pilot study patients who experienced care that did not meet the guidelines suffered an adverse outcome, compared with about 10 percent of patients whose care met the guidelines. For semi/unskilled care, about 38 percent of the pilot. patients who experienced care that did not meet the guidelines suffered an adverse outcome, compared with about 8 percent of the patients whose care met the guidelines. Overall, about 44 percent **of** the pilot study patients who experienced care that did not meet the guidelines suffered an adverse outcome, compared with about 16 percent of the patients whose care met the guidelines. Using the Chi-square statistic to assess the relationship between the adequacy of care and the presence of an adverse outcome, we find that the differences in the incidence of adverse outcomes are

TABLE B.1

ADVERSE OUTCOMES AMONG PATIENTS EXPERIENCING CARE THAT RET AND DID NOT MEET THE GUIDELINES

BASIC GUIDELINES/OUTCOMES DURING WEEKS ONE THROUGH SIX[a] NOT CONTROLLING FOR PATIENT CHARACTERISTICS

Type of Guideline	Percent of Patients with Adverse Outcomes Uhen Care:		Effect of Care that Did Not Meet the Guidelines			Size of Sample for which Care:	
	Net Guidelines (A)	Did Not Meet Guidelines (B)	Difference (C = B - A)	Chl square Statistic	Ratio B/A	Ret Guidelines	Did Not Meet Guldellnes
Semi/Unskilled Care	0.47	37.50	29.03***	11.289	4.43	118	16
Skilled Care	9.71	30.77	21.06**	19.905	3.17	103	78
All Care	15.87	43.59	27.72***	12.471	2.75	63	78

NOTE: The unit of analysis Is the patient. The Chi square statistic has been used to test for statistical independence between the presence of an adverse outcome and adequacy of care variables for each type of guideline. Patients for whom we cannot determine adequacy of care or the presence of au adverse outcome (due to ● lsslug data) are excluded.

'Excludes patients for whom six-week interview data were not collected.

 *Statistically different from zero at the 10 percent slgnlflcance level.
'*Statistically different from zero at the 5 percent significance level.
'"Statlstlcally different from zero at the 1 percent significance level.

highly statistically significant for skilled care, semi/unskilled care, and all care.

Table B.2 presents ordinary least squares estimates of the effect of experiencing care that did meet the guidelines on adverse outcomes, using the patient as the unit of analysis and controlling for patient characteristics. These are regression-adjusted estimates of the percentages of patients who suffered adverse outcomes when care did and did not meet the guidelines. (Because the analysis using the patient as the unit of analysis was exploratory, we did not calculate **probit** estimates.) The estimates presented in Table B.2 for skilled care and for all care (for which patient characteristics are controlled) are very similar to those presented in Table B.1 (for which patient characteristics are not controlled). However, the estimates for unskilled care differ. When we control for patient characteristics at discharge, the estimated effect on adverse outcomes of care that did not meet the semi/unskilled guidelines is much smaller and no longer statistically significant. The difference in the results when we control for patient characteristics appears to be due partly to correlation between the measure of the adequacy of care for semi/unskilled care and measures of functioning. This correlation is particularly pronounced when the patient is the unit of analysis. It is possible that this correlation is a spurious artifact of the relatively small patient sample.

2. **Probit** Estimates

Tables B.3 and B.4 present the estimates of the **probit** coefficients for the Basic Guidelines (without correction for measurement problems) and for the Physician Visit Variant (with correction for measurement problems). The

TABLE 8.2

ADVERSE OUTCOMES AMONG PATIENTS EXPERIENCING CARE THAT MET AND DID NOT MEET THE GUIDELINES

BASIC GUIDELINES/OUTCOMES DURING WEEKS ONE THROUGH SIX[a]
CONTROLLING FOR PATIENT CHARACTERISTICS

Type of Guideline	Percent of Observations with Adverse Outcomes When Care:		Effect of Care that Did Not Meet Guidelines		Ratio B/A	Size of Sample for Which Care Did Not Meet Guidelines:	
	Met Guidelines	Did Not Meet Guidelines	Difference (C = B - A)	t-Statistic		Met Guidelines	Did Not Meet Guidelines
Semi/Unskilled Care	11.37	15.82	4.45	.681	1.39	118	16
Skilled Care	9.32	31.27	21.95"'	2.893	3.36	103	78
All Care	20.19	40.11	19.92"'	2.979	1.99	63	78

NOTE: The unit of analysis is each applicable guideline. Differences between the adequately and inadequately cared for groups are estimated using multiple regression to control for the characteristics of individual patients at discharge.

[a] Excludes patients for whom six-week interview data were not collected.

'Statistically different from zero at the 10 percent significance level, using a one-tailed test.
"Statistically different from zero at the 5 percent significance level, using a one-tailed test.
"'Statistically different from zero at the 1 percent significance level, using a one-tailed test.

TABLE 8.3

ESTIMATES OF COEFFICIENTS OF THE **PROBIT** MODEL:
ALL CARE UNDER THE BASIC GUIDELINES

Variable	Maximum Likelihood Estimate	Standard Error
Care Met Guidelines	-0.367*	0.151
Impairment in Typical Week		
Meal preparation	0.290	0.206
Medications	0.384*	0.157
Bathing	-0.479*	0.268
Dressing	-0.195	0.256
Walking	-0.019	0.193
Toileting	0.312	0.207
Transfer	0.534*	0.195
Eating	-0.249	0.218
Impairment at Discharge		
Bathing	0.104	0.187
Toileting	0.855*	0.261
Transfer	-0.730*	0.260
Eating	-0.035	0.211
Severe cognitive or emotional impairment	-0.440*	0.210
Severity of Illness		
Stage 3 illness	-0.098	0.212
Significant comorbidity	-0.394*	0.162
Female	0.220	0.147
Education	0.075	0.101
Age	-0.005	0.009
Previous Use of Personal Care Aide	-0.020	0.235
Constant	-1.248	**0.793**

NOTE: -2 times the log likelihood ratio = 61.783 and is distributed as Chi
squared with 20 degrees of freedom.

*Statistically significant at the 5 percent level.

TABLE 8.4

ESTIMATES OF COEFFICIENTS OF THE **PROBIT** MODEL:
ALL CARE UNDER **PHYSICIAN** VISIT VARIANT

Variable	Maximum Likelihood Estimate	Standard Error
Care Met Guidelines	**-0.654***	0.169
Impairment in Typical Week		
Meal preparation	0.417"	0.230
Medications	**0.341***	0.170
Bathing	-0.413	0.293
Dressing	-0.466	0.290
Walking	-0.047	0.211
Toileting	**0.360***	0.211
Transfer	0.398"	0.204
Eating	-0.006	0.229
Impairment at Discharge		
Bathing	0.088	0.186
Toileting	**0.776***	0.258
Transfer	**-0.863***	0.271
Eating	0.244	0.230
Severe cognitive or emotional impairment	**0.468***	0.222
Severity of Illness .		
Stage 3 illness	-0.217	0.242
Significant comorbidity	-0.169	0.176
Female	0.271	0.170
Education	0.079	0.106
Age	-0.002	-0.010
Previous Use of Personal Care Aide	0.109	0.245
Constant	-1.497	0.848

NOTE: -2 times the log Likelihood ratio is 59.46 and is distributed as Chi
squared with 20 degrees of freedom.

* Statistically significant at 5 percent level.

latter represents the optimal specification of our model, assuming **that** the goal is **to** maximize the estimated impact of care that did not meet the guidelines on adverse outcomes. The estimates of the **probit** coefficients for the other models may be obtained from the author.

E.   SAMPLE DESIGN

In this section, we consider the design of the patient sample, the patient sample as implemented, and the design of the hospital sample.

1.   <u>Design of the Patient Samnles</u>

The key analyses involving patient samples are the clinical case-by-case review to assess the validity of the guidelines and their linkage to adverse outcomes, the analysis of the likelihood of adverse outcomes when care met and did not meet the guidelines (also to assess the validity of the guidelines), and the analysis of the effectiveness of the screen at identifying high-risk cases.

a. <u>Overview of Patient Samnles</u>

A judgmental sample of 100 cases was required for the clinical review; **these 100** cases were to include some relatively rare types of patients. To identify a. sufficient sample of these rare cases **and** to obtain a sufficient sample to support the analysis of the effectiveness of the screen and the analysis of the likelihood of adverse outcomes, we estimated that observations were necessary for at least 205 (116 high-risk and 89 low-risk) patients. **(We** describe the calculation of this sample size below.) Due to sample attrition and because high-risk patients were believed to comprise a relatively small minority of the population, we estimated that it would be necessary to process

B.16

sample intake data for almost 1,500 patients discharged from the hospital, complete screening interviews for over 1,000 patients (to identify our sample), and complete two-week interviews for over 240 patients to obtain an analysis sample of 205.   The two-week interview was also conducted for 25 cases screened out as not requiring care; they are not included in the total of 240. We describe the calculation of the number of completions required to obtain the desired samples below. As a convenience for the reader, we present here Table B.5, which summarizes the desired sample sizes for the key analyses, and Table B.6, which summarizes the number of completions that we estimated were required to obtain these sample sizes.

b.   Design of the Patient Sample

We used an iterative process to determine the sample sizes necessary to support the key analyses of the pilot study. While the most economical sample for the analysis of the effectiveness of the screen would also support the analysis of the likelihood of adverse outcomes, this was not true for the case-by-case clinical review.   To find the most economical sample which would support all these analyses, we iterated.   The most economical sample for analyzing the effectiveness of the screen divided the sample equally between the patients at high risk and patients not at high risk: **however,** this sample would not produce the number of patients who experienced the care that did not meet the guidelines and suffered adverse outcomes that was desired for the case-by-case clinical review.

The iterative process began with the sample for the case-by-case clinical review.   For the clinical review, we desired approximately 33 cases in which patients experienced care that did not meet the guidelines and also suffered

TABLE B.5

DESIRED SAMPLE SIZES FOR KEY ANALYSES

Clinical Case-by-Case Review	100
Statistical Analysis of the Validity of the Guidelines	205
Effectiveness of Screen	205

TABLE B.6

DESIRED NUMBER OF COMPLETIONS FOR PILOT STUDY

	Completions
1. Hospital discharges processed	1,499[a]
2. Initial sample	1,259[a]
3. Screens completed	1,007[b]
4. Two-week interview completed	266[c]
5. Six-week interview completed	205[d]
6. Abstracts	266[e]
7. Clinical review	100[f]

[a] Includes only those discharged to the community.

[b] We assumed that screens would be completed for 80 percent of those for whom they were attempted.

[c] We assumed that 15 percent of those who were screened in were at high risk of experiencing care that did not meet the guidelines and of suffering adverse consequences. Of these, 90 percent were assumed to complete the two-week interview (1,007 x .15 x .9 = 136), yielding 136 risk cases at the two-week interview. In addition, the two-week interview was to be conducted for 25 cases screened out as not needing care and 105 cases needing care but not at high risk.

[d] We assumed that 85 percent of those who completed the two-week questionnaire would complete the six-week questionnaire.

[e] We assumed that abstraction would be conducted for those for whom two-week data were available, plus 25 cases screened out as not needing aftercare.

[f] A subset of 100 of the 205 cases that met certain criteria were selected for clinical review. These criteria are discussed in Markson et al., 1989.

adverse outcomes; 33 in which they experienced care that did not meet the guidelines but not adverse outcomes: and 33 in which they suffered adverse outcomes but experienced care that met the guidelines. We anticipated that those who experienced care that did not meet the guidelines **and** who suffered adverse outcomes would be the rarest of these three types of cases. If we selected a sample large enough to obtain the desired number of this type of case, we expected to identify a more than sufficient number of the other two types of cases.

There were little or no data on which to base our estimates of the proportions of patients likely to experience care that did not meet the guidelines and to suffer adverse outcomes. (One goal **of** the pilot study was to develop preliminary estimates of these proportions.) However, two studies provided some guidance. Lindenberg and Coulton (1980) report that 35 percent of the patients in their study who needed nursing or personal care received inadequate post-hospital **care**.[1] With respect to the risk of adverse outcomes, **Berkman** et al. (1986) report that two-thirds of a sample of elderly cardiac patients determined to be at high risk of poor recovery (based on their score on the Geriatric Functional Rating Scale **[GFRS]**[2]) were readmitted to the hospital within four months. While both studies involve small samples and while we could not be sure how their composition compared with that of our sample, they provided a starting point.

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[1]**Later** in this section, we consider the proportion who needed care.

[2]**The** GFRS takes into account functioning, support from the community, informal support, and financial situation. These 18 patients had scores of 50 **or** below on the **GFRS.**

Assuming that the Lindenberg and Coulton data reflected care that did not meet the guidelines among the high-risk group, and that the Berkman et al. data reflected the incidence of adverse outcomes among that group, we estimated that about 25 percent of the high-risk group (.35 x .67 = .23) would experience care that did not meet the guidelines and suffer adverse outcomes. This estimate of 25 percent was insensitive to moderate changes in the underlying assumptions. For example, given that the Lindenberg and Coulton study did not explicitly select patients at high risk, it was reasonable to assume that their finding of 35 percent who experienced inadequate care might be an understatement for a high-risk group. If we had assumed that 45 percent of the high-risk group experienced care that did not meet the guidelines (rather than 35 percent) but that only 50 percent of this group experienced adverse outcomes (rather than 67 percent), we still obtained an estimate of about 25 percent who experienced both (.45 x .50 = .23).

Using the assumption that 25 percent of the high-risk group would experience care that did not meet the guidelines and would suffer adverse outcomes, we calculated that between 110 and 120 high-risk patients would be required to identify 33 cases who experienced both. A sample of 110 high-risk cases would yield 28 high-risk cases (110 x .25 = 28) who experienced both, and a sample of 120 would yield 30 such cases (120 x .25 = 30)--that is, most of the 33 cases of patients who experienced both that we desired for the clinical review. A much smaller proportion of the patients not at high risk would also experience care that did not meet the guidelines and suffer adverse outcomes. We assumed that this proportion was 5 percent. Thus, a sample of

80 to 90 patients not at high risk would yield 4 or 5 patients who experienced care that did not meet the guidelines and suffered adverse outcomes.

At this point in the iterative process, we considered the sample size required for analyzing the effectiveness of the screen. A total sample of about 200 divided equally between high- and low-risk groups would give us adequate statistical power for comparing the proportions who experienced adverse outcomes in the high- and low-risk groups. However, as we have seen, a sample of 100 high-risk cases was not sufficient for the case-by-case clinical review. If the sample of about 200 was not to be divided equally between the high- and low-risk groups, a larger total sample would be required to maintain the same statistical power for an analysis of the effectiveness of the screen.

Working back and forth in this manner between the two analyses, we calculated that the most economical sample which would support both analyses would consist of 116 patients at high risk and 89 patients not at high risk, for a total of 205. Under the assumption that 25 percent of the high-risk group and 5 percent of the low-risk group would experience care that did not meet the guidelines and suffer adverse outcomes, a sample of 116 high-risk and 89 low-risk cases should have enabled us to identify 29 patients in the high-risk group'who experienced care that did not meet the guidelines and suffered adverse outcomes ($116 \times .25 = 29$) and 4 such patients in the group not at high risk ($89 \times .05 = 4$), for the desired total of 33.

Returning to the analysis of the effectiveness of the screen, a sample of 116 high-risk and 89 low-risk cases would enable us to detect a 15 percentage point difference between the groups at high risk and not at high

risk with adequate statistical power. For example, if 10 percent of the group not at high risk and 25 percent of the group at high risk actually experienced care that did not meet the guidelines and suffered adverse outcomes, the a priori probability that the estimate from this sample would be statistically significant was 88 percent.[3] It was not necessary to be able to detect small differences in the proportions of patients who experienced care that did not meet the guidelines and who suffered adverse outcomes in the groups at high risk and not at high risk. If the difference was small, we could conclude that the screen was not functioning effectively.

We indicated above that a sample of sufficient size to support an analysis of the screen would also support an analysis of the likelihood of adverse outcomes. In the latter analysis, we would compare adverse outcomes when care met the guidelines with those when it did not. Assuming (1) that the average number of guidelines applicable to a patient was four: (2) that half of the applicable guidelines were not met when any was failed: and (3) that 35 percent of patients at high risk experienced care that did not meet the guidelines (following Lindenberg and Coulton), and that 10 percent of patients not at high risk experienced such care, we would have a sample of 81 observations in which care did not meet the guidelines for high-risk patients (116 x 4 x .5 x .35) and 18 such observations for low-risk patients (89 x 4 x .5 x .10) , for a total of 99 observations in which care did not meet the guidelines. Under the same assumptions, we would have 720 observations ([205

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[3]In calculating the power, we used a one-tail test because we assumed that the proportion who experienced care that did not meet the guidelines and suffered adverse outcomes would be larger for the high-risk group. The calculation also assumed a 5 percent significance level.

x 4] - 100) in which care met the guidelines. With a sample of this size, we expected to be able to detect moderate differences in the likelihood of adverse outcomes when care met and did not meet the guidelines. For example, assume that adverse outcomes are suffered in the population for 20 percent of the cases in which care that did not meet the guidelines, compared with 10 percent of the cases in which care met the guidelines. The a priori probability that the sample estimate of the difference would be statistically significant was about **0.88.**[4]

c. Two- and Six-Week Interviews and **Hospital** Abstracts

As discussed above, we calculated that a sample of 205 (116 high-risk and 89 low-risk cases) was sufficient to support the analyses to address the key issues in the pilot. To obtain all the data we required for this sample, we had to complete medical records abstracts and conduct two-week and six-week interviews. Due to attrition between the two-week and six-week interviews, the number of two-week interview completions required was slightly larger. If we assumed that 85 percent of those who completed the two-week interview would complete the six-week interview, we needed to complete 241 two-week interviews **(205/.85 =** 241) to obtain data on 205 patient8 at **six** weeks. We planned to abstract medical records for the 241 patients on whom two-week interview data were collected because the schedule for the pilot study did not permit us to wait until after the six-week interview to begin medical records abstraction.

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[4]**We** assumed that the effective sample size was reduced by 10 percent due to the non-independence of the observations, a one-tailed test, and a 5 percent significance level.

In addition to the 241 two-week interviews and abstracts necessary to obtain the sample of 205 patients, we also conducted the two-week interview and abstracted medical records for a sample of cases identified by the screening procedures as not requiring care. We included 25 such cases, for a total of 266 two-week interviews and abstracts. Twenty-five cases were sufficient to indicate whether a non-trivial proportion of cases who needed care were being screened out inappropriately. We estimated that a sample of 25 cases would give us a 95 percent confidence interval of about plus or minus 12 percentage points around the observed proportion of cases identified as not needing care according to the screening procedures but determined to need care based on a review of the full medical record.[5] For example, if we observed one case in 25 that was inappropriately screened out (that is, 4 percent of our sample), we could be confident that the percentage in the population was no more than 16 percent. While this was not very precise, doubling the sample to 50 cases would not have substantially reduced the width of the confidence interval. With a sample of 50, if we observed 4 percent that were inappropriately screened out, the confidence interval would be plus or minus 8 percentage points, and we could have been confident that the percentage in the population was no more than about 12 percent. In our judgment, the increase in precision (that is, confidence intervals of plus or minus 8 versus 12) did not warrant the expense of abstracting the full medical record and conducting the two-week interview for additional cases.

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[5]In calculating the confidence interval, we assumed that in the population 10 percent of the cases screened out actually needed care.

d. Screening and Sample Intake

Deriving the sample size for the screen and calculating the number of cases required for the initial sample for which screening would be attempted began with the requirement of 241 two-week interviews (136 at high risk and 105 not at high risk) .[6] We expected that the high-risk group would be the rarer of the two groups; therefore, if we screened in a sufficient sample of patients at high risk, we would also identify a more than sufficient number of patients not at high risk, and a random sample of these patients could be selected for the analysis.

Once again, little data were available to help us estimate the proportion of Medicare patients discharged to the community who were at high risk. However, Berkman et al. (1986) contain some useful information. Out of 60 elderly cardiac patients, they found that 28 (30 percent) were at high risk, based on their score on the GFRS. Because the Berkman et al. sample was restricted to cardiac patients, we assumed that it might overstate the proportion of patients who were at high risk across diagnoses. Certainly, the proportions of patients who need skilled care should differ across diagnoses. The Lindenberg and Coulton (1980) study is based on patients with a variety of diagnoses, and they report that about half of their sample needed nursing care and half personal care. We assumed, conservatively, that only half of our sample would need either nursing or personal care, and that 30 percent of those who needed care would be at high risk, thus obtaining an estimate that 15 percent of those screened in would be at high risk.

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[6]The sample sizes for the high- and low-risk groups were also inflated for an attrition rate of .85 between the two- and six-week interviews (1161.85 = 136: 89/.85 = 105).

Using the assumption that 15 percent of Medicare **dischargees** would be at high risk, and assuming that 90 percent of those who completed the screen would complete the full two-week interview, we obtained an estimate of 1,007 as the number of completed screens required to obtain 136 high-risk cases at two weeks **(136/.9/.15 =** 1,007). To derive the number of cases for which screening would be attempted, we assumed that 80 percent of the patients contacted would complete the screen. Thus, at intake, we assumed that we had to identify 1,259 cases for the initial sample to yield 1,007 completed screens **(1,007/.80 =** 1,259). Given that 84 percent of Medicare discharges are made to the community,' we calculated that we would have to process 1,499 discharges to identify 1,259 discharged to the community **(1,259/.84 =** 1,499).

2. Patient **Sample** Obtained

In the previous section, we described our design for the patient samples in the pilot study and the assumptions underlying that design. As indicated there, we had very little data on which to base these assumptions. Consequently, it is not surprising that some of these assumptions were not borne out. The design of the patient samples was adjusted during fielding to respond to new information on assumptions. The most critical assumption pertained to the percentage of patients identified as at high risk. The revision to the sample design involving this assumption are described below. In addition, the change in this assumption affected other aspects of data collection, including the number of cases that would have to be screened and the number of discharges that would have to be processed.

'Washington **Report** on Medicine and Health, January 7, 1985.

The percentage of patients identified as at high risk was **higher** than we had assumed it would be. Our a priori assumption was that 15 percent of Medicare patients discharged to the community would be identified as at high risk. Because this assumption was so critical, we calculated the percentage of patients actually being identified as in the high risk group after fielding had been underway for a time. A calculation based on the first 320 cases screened indicated that the percentage of patients being identified as at high risk was 45 percent, a much larger percentage than we had assumed. Our response to this was to review the risk classification procedures. During this review, we identified several measures used in the risk classification procedures that were problematic. The risk classification procedures were reviewed so that these problematic measures were no longer relied upon in determining risk. (Chapter IV contains a discussion of the revised procedures.) Under the revised procedures, slightly over 20 percent of the Medicare patients being discharged to the community were identified as at high risk.

By the time we completed the review of the risk classification procedures and **reached** agreement on the appropriate way to proceed, the two-week interview had been completed on a number of patients who were at high risk under the original procedures but not under the revised procedures. The original sample design had called for sampling the high-risk group with certainty and selecting a random subsample (initially 18 percent) of the **low-**risk group. Because they had been assigned previously to the group at high risk, patients who were at high risk only under the original procedures had been sampled with certainty, and were thus oversampled relative to other

patients not at high risk. Sampling from the group at high risk only under original procedures was discontinued when the revised risk classification procedures were implemented. However, there were now three risk groups sampled at different rates: (1) patients at high risk under both the original and revised procedures: (2) patients at high risk only under the original procedures; and (3) patients not at high risk under the original procedures. Records were maintained on the revised risk groups to make it possible to weight the data to produce preliminary estimates of the percentages of all patients who experienced care that did not meet the guidelines and suffered adverse outcomes.

The sample design for the two-week and six-week interviews and the medical records abstraction were revised to take into account the fact that there were now three risk groups, that patients at high risk only under the original procedures were oversampled, and that their observations were of less value in the analysis of the effectiveness of the screening procedures than were observations on patients not at high risk under the original procedures. They were of less value because patients at high risk only under the original procedures were not representative of all patients not at high risk. The analysis of the effectiveness of the screening procedures required an adequate sample of the group not at high risk so that we could compare the experiences of patients at high risk and not at high risk. The experiences of patients at high risk under the original procedures . but not under the revised procedures might be more similar to those of patients at high risk than to the experiences of patients who were not at high risk under the original procedures. To maintain statistical power under the revised design, we

planned somewhat larger samples than those required under the original design. Table B.7 represents the total number of planned completions by risk group for the data collection activities under the revised sample design. Under the revised design, the sample for which two-week interview data and medical records were to be abstracted was 260, compared with 205 under the original design. To conserve resources, we planned to conduct the six-week interview only for a portion of the patients for whom the two-week interview and medical records abstraction were completed.

Primarily because attrition rates were lower than had been anticipated, the actual number of completions and sample sizes were somewhat larger than anticipated. (Information on the number of completions by data collection activity is presented in Chapter V.) The analysis sample consisted of 299 cases; 273 of these cases were in the risk groups discussed above. In addition, there were 26 cases that had been screened out as not needing care. Because a number of these 26 cases were later determined to need care under the guidelines (the screening procedures had incorrectly identified them as not needing care), we included the 26 cases in the analysis sample. Table B.8 presents the distribution of these 299 cases by risk group.

3. **Hospital Sample**

The sample of hospitals for the pilot study was judgmental. The criteria for the selection of hospitals were developed with three issues in mind: (1) the necessity of learning **about the** willingness of hospitals to cooperate: (2) the necessity of learning about the feasibility of our data collection procedures: and (3) the necessity of testing the validity of the guidelines in communities with different practice patterns and resources.

TABLE 0.7

DESIRED NUMBER OF COMPLETIONS AFTER REVISION
OF RISK CLASSIFICATION PROCEDURES

	Screening Interview Complete[a]	Full Two-Week Interview Complete[a]	Six-Week Interview Complete	Medical Records Abstraction Completed
At High Risk under Revised Procedures	174	162	129	142
At High Risk Only under Original Procedures	159	94	40	60
Not at High Risk under Original Procedures	462	61	58	58
Total[b]	795[c]	317	227	260

NOTE: A total of 1,264 intake forms were processed: however, screening interviews were never attempted for 285 of these.

[a]Includes partial completions (that is, cases in which the patient interview was completed, but the caregiver interview was not).

[b]Excludes patients identified as not needing care according to screening procedures.

[c]Screening interviews were also completed for 51 patients who were determined not to need care according to the screening procedures, for a total of 846 completed screens.

TABLE B.8

DISTRIBUTION OF ANALYSIS
SAMPLE BY RISK GROUP

	Number of Observations
At High Risk under Original and Revised Procedures[a]	140
At High Risk Only under Original Procedures[b]	70
Not at High Risk under Original Procedures[c]	63
No Care Needed According to Screening Procedures[d]	26
Total	299[e]

[a] This group is identified as the high-risk group in the body of this report.

[b] This group is identified as the moderate-risk group in the body of this report.

[c] This group is identified as the low-risk group in the body of this report.

[d] These cases were not classified as at risk until it was determined in the analysis phase that a number of patients in this group needed care under the guidelines.

[e] Includes patients for whom six-week interview data were not collected.

The cooperation of hospitals and the feasibility of our data collection procedures might have varied according to several hospital characteristics. The cooperation of hospitals was likely to vary according to ownership/ auspices ; for-profit hospitals might be less willing to participate. The feasibility of data-collection was likely to be affected by differences in recordkeeping systems, which, in turn, were likely to vary according to the size of the hospital and membership in a chain, and might also vary by the type and location of the hospitals-- for example, teaching hospitals, hospitals in medical centers, and hospitals in rural areas. In addition, recordkeeping systems for ambulatory surgery patients might differ . We distributed our judgmental sample of hospitals to include hospitals which varied according to the following factors :

o   Bed size

o   Ownership/auspices, including membership in a chain

o   Urban/rural location

o   Teaching status

o   Medical center

o   Presence of ambulatory surgery center

To ensure the inclusion of different practice patterns and different levels of resources, we also selected hospitals that varied according to:

o Average length of hospital stay in the state*

_____

*Based on the 50 most frequent DRGs in a recent year (data were supplied by HCFA).

o The availability of home health care[9]

The judgmental sample included hospitals in two states in two different areas of the country. These states were Ohio and Washington. Washington has a short average length of stay (6.86) ; and Ohio, a long average length of stay (10.36). The sample included four hospitals in each of two states, for a total of eight hospitals. Two of the eight hospitals chosen were small (fewer than 100 beds), two were of moderate size (100 to 299 beds), and four were large (300 beds or more). Two of the hospitals were in rural areas (that is, in counties not in a metropolitan statistical area) as defined by the U.S. Census Bureau (as of June 1983). Although the communities served by these rural hospitals were likely to be relatively poor in community care services, we included one hospital in a non-rural area which had a relatively poor home care service environment, as measured by the number of Medicare home health visits per elderly individual.

To ensure the cooperation of at least eight hospitals, a larger number were contacted. Nine of the hospitals contacted agreed to participate and were included. The characteristics of these hospitals are described in Chapter V.

To determine how many weeks of sample intake were required under the assumption that eight hospitals would be participating (2 small, 2 medium, and 4 large) , we estimated how many patients eligible for our study would be discharged from an average hospital of each size during a one-week period. The number of admissions in 1985 to short-term hospitals of different sizes

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[9]Based on county data on the number of Medicare home health visits.

in the United States was available from the American Hospital Association's (AHA) annual survey. [10]   Dividing these figures by 52 yielded an 'estimated average of 320 admissions a week in large hospitals, 116 a week in medium hospitals, and 30 a week in small hospitals.   We assumed that 26 percent of these would be Medicare patients."   We also assumed that 84 percent of the Medicare admissions were discharged into the community (that is, to home health agency or home or self-care).   Under these assumptions, over a four-week period, we estimated that 1,373 Medicare patients would be discharged to the community from the eight hospitals.[12]   Comparing this number to the 1,259 patients for whom we estimated that screening interviews must be attempted, we found that a four-week sample intake period would be sufficient.

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[10]Table 2A, Hospital Statistics, 1986 Edition, American Hospital Association.

[11]HCFA 'has provided us with unpublished data on the number of hospital discharges for aged Medicare beneficiaries.   The total for 1984 (the latest year for which complete data are available) was 9.7 million.   This figure includes end-stage renal disease beneficiaries under age 65 (those 55 to 65 are included in our sample).   Separate statistics on these groups are not available.   Nevertheless, the figure is sufficiently accurate for our purposes.   Using the total number of admissions to all short-term hospitals from the AHA's annual survey, we estimate that, in 1984, these 9.7 million discharges represented 26 percent of all discharges.   .

[12]We would obtain 1,118 from the four large hospitals in four weeks (320 x .26 x .84 x 4 x 4 = 1,118): 203 from the medium hospitals (116 x .26 x .84 x 4 x 2 = 203); and 52 from the small hospitals (30 x .26 x .84 x 4 x 2 = 52).

APPENDIX C:

PRELIMINARY ESTIMATES TO INFORM **THE** NATIONAL STUDY

A national study will be quite expensive, and it is thus important that information collected in the pilot study be used to assess whether the adequacy of access to post-hospital care is a serious enough problem to warrant a national study. Preliminary estimates of the extent to which care needs are not met under the guidelines and adverse outcomes are suffered would be useful in such an assessment, as would descriptive information on the nature of inadequacies and adverse outcomes.

In addition, the sample design for a national study would benefit from pilot study estimates of (1) the percentage of Medicare patients who are discharged to the community who fall into the various risk groups ; and (2) the percentage of patients at various risk levels who experience care that does not meet the guidelines and who suffer adverse outcomes.

The sample in the pilot study supports only <u>preliminary</u> estimates of these percentages. For three reasons, these estimates should be used with caution. First, patients in the pilot study data may not be representative of hospitalized Medicare patients across the nation. The pilot study included only a very small number of hospitals (nine) in two states and a relatively small sample of patients (299 in the analysis sample). Second, the hospitals in the pilot study were not chosen randomly. Thus, patients included in the pilot study may differ in unknown ways, from Medicare patients across the nation who are discharged from an acute care hospital. Finally, due to the substantial amount of missing data in the pilot study, some of the estimates are sensitive to the assumptions made about cases with missing data.

1. <u>Preliminary Estimates of the Extent to Which Guidelines Are Not Met</u>

Table C.l presents preliminary estimates of the average percentage of applicable guidelines that are **not** met for Medicare patients discharged to the community and the percentage of Medicare patients for whom one or more guidelines are not met under the Basic Guidelines.

The estimates in Table C.l were calculated both with a sample that excludes cases with missing data and a sample that includes with cases with missing data under the assumption that care met the guidelines for the conditions for which data are missing. For reasons discussed in Appendix B, the exclusion of cases 'with missing data may <u>understate</u> the extent to which guidelines are met. On the other hand, the inclusion of cases with missing data (under the assumption that care met the guidelines) may <u>overstate</u> the extent to which the guidelines are met. Because the amount of missing data is substantial, we present estimates calculated both ways. This allows us to bound our estimate.

As Table C.l indicates, we estimate that 20 to 26 percent of all the care needs of Medicare patients under the Basic Guidelines were not met, and that 43 to 55 percent of Medicare patients experienced some care that did not meet these guidelines (that is, one or more guidelines were not met). These data indicate that, while a substantial minority, or even a majority, of Medicare patients experienced some post-hospital care that did not meet these guidelines, the majority of the care needs of most patients were met. A further investigation indicated that half or more of the care needs were met for over 70 percent of the patients whose care did not meet one or more guidelines. [1]

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[1] Because these estimates exclude the cases with missing data, they may understate the extent to which care needs were met.

TABLE C.1

PRELIMINARY ESTIMATES OF THE EXTENT TO WHICH THE CARE OF
MEDICARE PATIENTS DID NOT MEET GUIDELINES FOR POST-HOSPITAL CARE:
BASIC GUIDELINES

Measure	Mean	Standard Error	95% Confidence Interval
Percent of Applicable Guidelines That Were Not Met (per patient)			
Cases with missing data excluded	25.98	3.76	18.61 - 33.35
Cases with missing data included and assumed to represent adequate care	20.20	3.03	14.26 - 26.14
Percent of Patients With Care That Did Not Meet One or More Guidelines			
Cases with missing data excluded	55.38	4.25	47.05 - 63.71
Cases with missing data included and assumed to represent adequate care	43.17	3.73	35.86 - 50.48

In Chapter III, we described a variant of the guidelines, the Physician Visit Variant. Under this variant, physician visits are counted toward meeting the specifications on the number of professional visits for eight conditions beyond those specified under the Basic Guidelines. As discussed in Chapter III, the Physician Visit Variant performed somewhat better than did the Basic Guidelines in our analysis of the relationship between care that did not meet the guidelines and the presence of adverse outcomes, and thus appears to provide a better specification of minimally adequate care.

Under the Physician Visit Variant, we estimate that from 19 to 28 percent of all the care needs of Medicare patients were not met and that 39 to 57 percent of Medicare patients experienced some care that did not meet guidelines under the Physician Visit Variant. As for the comparable percentages on the Basic Guidelines, the lower end of these ranges were calculated under the assumption that care was adequate when an observation was missing and the upper end of the ranges were calculated after excluding cases with missing data.

Table C.2 presents information on the types of specifications that were not met for the observations in which care did not meet the Basic Guidelines. (The unit of analysis in this table is each applicable guideline.) As the table indicates, the vast majority of the specifications that were not met are specifications involving skilled care. Only about 13 percent of all the specifications that were **not** met involve semi/unskilled care. The proportions are similar for the Physician Visit Variant: under that variant 12 percent of all the specifications that were not met involve semi/unskilled care.

TABLE C.2

TYPE OF GUIDELINE SPECIFICATIONS THAT WERE NOT MET:
BASIC GUIDELINES

Specification	Number	Percent
Skilled Care		
Care Did Not Meet Specification on:		
Number of professional visits	155	**54.96**
Timing of initial visit	82	**29.08**
Other	8	2.84
Semi/Unskilled care		
Any Specification	37	13.12
Total	282	100.00

[a]A total of 282 specifications were not met in 215 observations in which care did not meet the guidelines. The same patient may have had multiple observations on different guidelines, and multiple specifications **may** have been failed for each observation.

Fifty-five percent of all the specifications that were not met under the Basic Guidelines involve the number of professional visits and 29 percent involve the timing of the initial visit. A failure to meet the guideline specification on the number of professional visits is associated with a failure to meet the guideline specification on the timing of the initial visit. The specification on the timing of the initial visit was not met in over 90 percent of the cases in which the specification on the number of professional visits was not met (and data on the number of visits and the timing of the initial visit were available).

A further examination of the observations in which care did not meet the specifications for skilled care under the Basic Guidelines indicates that between 40 and 52 percent of the sample members for whom this was the case had no professional visits in the two weeks after discharge, depending on the treatment of missing data. [2] The comparable range under the Physician Visit Variant is 39 to 54 percent. Weighting our sample to reflect the Medicare population, we estimate that between 41 and 55 percent of Medicare patients whose care did not meet the Basic Guidelines for skilled care had no professional visit. The comparable range under the Physician Visit Variant is 40 to 56 percent.

The observations for which care did not meet the guidelines are distributed reasonably well across the guidelines. Although care that did not meet the guidelines was not observed for eleven guidelines (seven of these guidelines were never applicable), no single guideline accounts for more than

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[2]The lower end of the range is calculated under the assumption that all missing data represents adequate care. The upper end of the range is calculated with missing data excluded.

about 13 percent of the observations in which care did not meet the guidelines. (See Tables III.3 and III.4 for the distribution of pilot study observations in which care did not meet the skilled and semi/unskilled guidelines.)

Figures C.l and C .2 present highlights of the results on care needs under the Basic Guidelines using (respectively) each applicable guideline and the patient as the unit of analysis. Figure C.la is based on information from Table C. 1, which indicates that between 20 to 26 percent of care needs of Medicare patients under the Basic Guidelines were not met (depending on the treatment of missing data): Figure C.la presents the midpoint of this range, 23 percent. Figure C.lb presents information from Table C.2 on the type of specifications that were observed as not met under the Basic Guidelines. (A figure for the Physician Visit Variant that is similar to Figure C.l is presented in the Executive **Summary.**) Figure **C.2a** is based on information from Table C.l, which indicates that between 43 to 55 percent of Medicare patients experienced care that did not meet one or more of the Basic Guidelines (depending on the treatment of missing data) ; Figure **C.2a** presents the midpoint of this range, 49 percent. Figure **C.2b** is based on information from the text of this appendix which indicates that 41 to 55 percent of Medicare patients whose care did not meet the Basic Guidelines for skilled care had no visits to a professional: Figure **C.2b** presents the midpoint of this range, 48 percent.
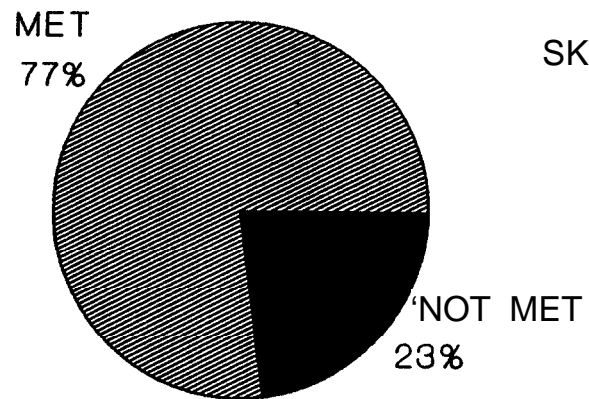
2. Preliminary Estimates on Adverse Outcomes

Table C.3 presents preliminary estimates of the extent of adverse outcomes which may be associated with inadequate care in the **immediate post-**
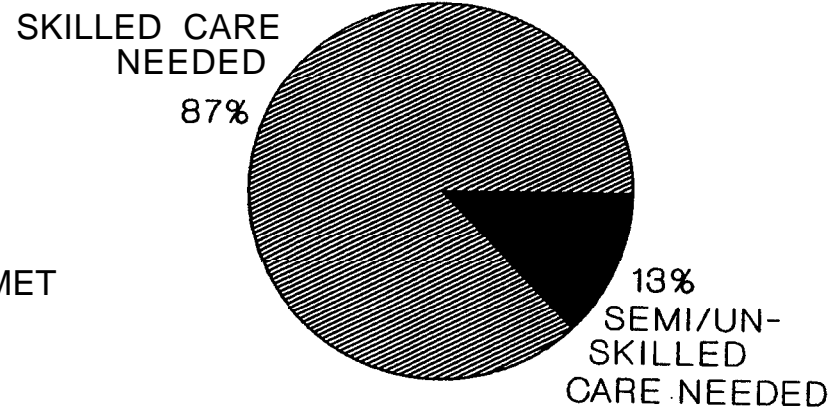
FIGURE C.I
CARE NEEDS UNDER BASIC GUIDELINES

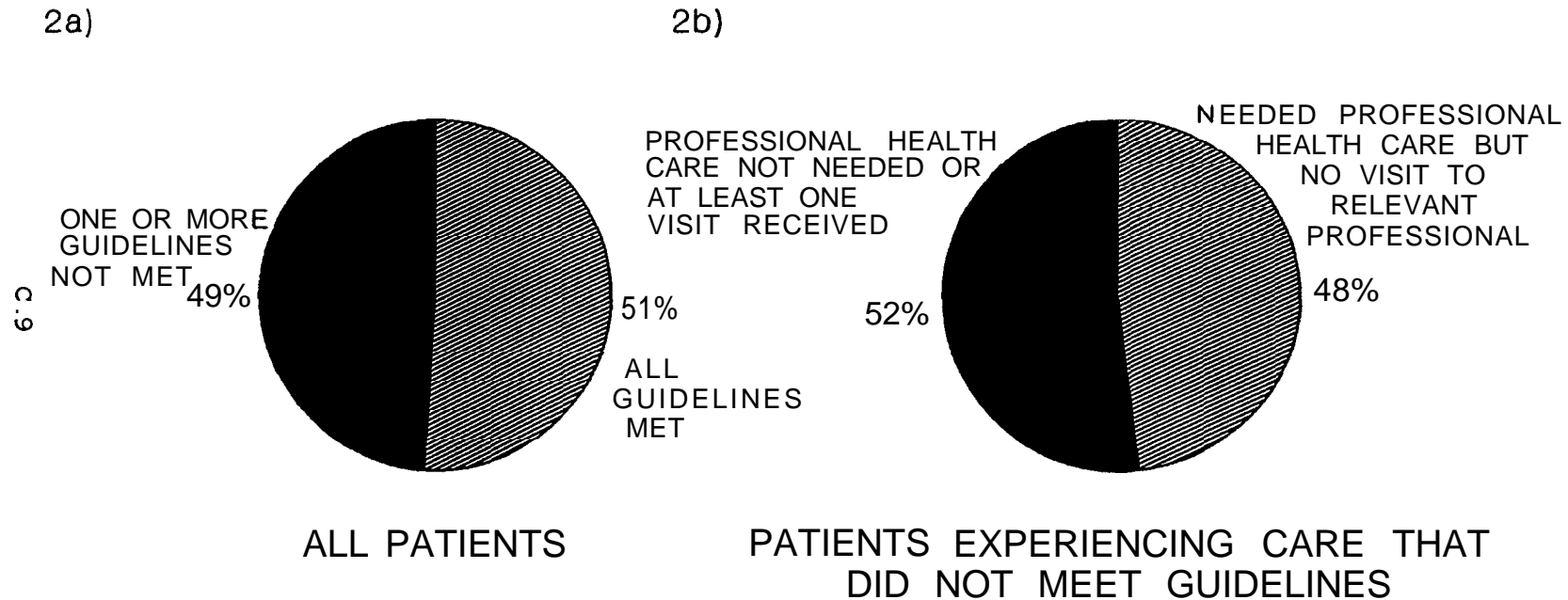1a)   1b)

ALL CARE NEEDS   UNMET CARE NEEDS

NOTE: When the estimates involve a range, the midpoint of
that range is used. The treatment of missing data
was varied in developing the range.

FIGURE C.2
PATIENT EXPERIENCE UNDER BASIC GUIDELINES

2a)   2b)

ONE OR MORE GUIDELINES NOT MET 49%

51%
ALL GUIDELINES MET

PROFESSIONAL HEALTH CARE NOT NEEDED OR AT LEAST ONE VISIT RECEIVED

NEEDED PROFESSIONAL HEALTH CARE BUT NO VISIT TO RELEVANT PROFESSIONAL

52%   48%

ALL PATIENTS   PATIENTS EXPERIENCING CARE THAT
                      DID NOT MEET GUIDELINES

NOTE: When the estimates involve a range, the midpoint of
      that range is used. The treatment of missing data
      was varied in developing the range.

TABLE C.3

PRELIMINARY ESTIMATES OF TEE EXTENT TO WHICH ADVERSE
OUTCOMES HERE **SUFFERED**

PROBLEMATIC MEASURES EXCLUDED
(Percent)

Measure	Mean	Standard Error	95% Confidence Interval
Percent of Applicable Guidelines with An Adverse Outcome[a]			
Cases with missing data excluded	**9.55**	2.58	4.65 - 14.45
Cases with missing data included and assumed to involve no adverse outcomes	4.40	1.55	1.36 - 7.44
Percent of Patients			
Cases with missing data excluded	**18.19**	3.32	11.68 - 24.70
Cases with missing data included and assumed to involve no adverse outcomes	13.10	2.55	**8.10 - 18.10**

NOTE: ⸜These estimates are applicable to both the Basic Guidelines and the Physician Variant.

[a] Single outcome events associated with more than one guideline applicable to a given patient are included multiple times. All applicable guidelines are included regardless of whether any adverse outcomes were specified for a particular guideline.

discharge period. Estimates are presented for the average percentage of applicable guidelines for which one or more adverse outcomes occur for Medicare patients discharged to the community and the percentage of such Medicare patients who suffer one or more adverse outcomes.

Estimates involving only adverse outcomes are identical for the Basic Guidelines and the Physician Visit Variant. The revisions to the Basic Guidelines to form the Physician Visit Variant do not affect adverse outcomes.

The problematic measures of outcomes for toileting and pain are excluded in Table C.3. As discussed in Chapter III, the outcome measures designed to measure impaction (one of the outcomes for toileting) and severe pain do not appear to have worked as intended. The measure of impaction appears to have picked up constipation, and the measure of pain (which asks about pain which interferes with sleep or everyday activities) appears to have picked up discomfort in addition to severe pain. Due to these measurement problems, these variables were dropped from our analysis of the link between care that did not meet the guidelines and adverse outcomes. In addition, two other adverse outcomes for the guideline on help with toileting (fall and urinary tract infection) were also deleted because they were not linked to the specification of minimally adequate care for the **Toileting** Guideline. Some of the reports of impaction, fall, and urinary tract infection (on the Toileting Guideline), and some of the reports of pain, are probably accurate: however, we have deleted all such reports in developing the estimates in which problematic measures were excluded. Thus, the estimates in which the problematic measures were excluded may understate the incidence of adverse outcomes. On the other hand, the estimates in which the problematic measures

were included almost surely overstate the incidence of adverse outcomes. Because it seems likely that the problematic measures are inaccurate in the majority of cases, we focus on developing bounds for our estimates based on differing treatment of missing data, with problematic measures excluded.

In Table C. 3, cases with missing data are both excluded and included under the assumption that adverse outcomes did not occur. As discussed in Appendix B, the exclusion of missing data tends to overstate the incidence of adverse outcomes; the inclusion of missing data (under an assumption of no adverse outcomes) tends to understate the incidence of adverse outcomes.

As Table C.3 indicates, we estimate that adverse outcomes occur for from 4 to 10 percent of all the guidelines applicable to Medicare patients discharged to the community and that from 13 to 18 percent of such patients suffer one or more adverse outcomes. If we include the problematic measures, the estimates are higher. For example, if the problematic measures are included, we estimate that from 17 to 23 percent of Medicare patients discharged to the community suffer **one** or more adverse outcomes.

As discussed in Chapter II, the measures of adverse outcomes associated with the guidelines involve (1) the unscheduled or unexpected use of health services (received from a hospital, nursing home, emergency room, or physician'soffice or clinic) due to a complication of the patient's condition or treatment or an exacerbation of the patient's condition; and (2) direct measures of morbidity which involve complications (e.g., pneumonia and contractures) and injury (e.g., fall and wheelchair injury). Because serious morbidity will tend to prompt the use of health services, the measures of service use generally reflect more serious outcomes than do the direct morbidity measures.

c.12

As Table C.4 indicates, most of the adverse outcomes that were observed in the pilot study data involve direct measures of morbidity. With the problematic measures included, we observed a total of 128 adverse outcomes in the pilot study analysis sample for weeks one through six.[3] Eighty percent ([96 t 7]/128) of these involve direct measures of morbidity. With the problematic measures excluded, 61 percent ([32 t 7]/[41 t 23]) of observations on adverse outcomes involve morbidity. The inclusion of the problematic measures tends to overstate the percentage of adverse outcomes that are morbidities and exclusion tends to understate this percentage, providing bounds for the estimate. Thus, we estimate that between 61 and 80 percent of the adverse outcomes we observed in weeks one through six were morbidities.

It is important to note that the direct measures of morbidity do not dominate the measures of adverse outcomes during weeks three through six. Only 30 percent (7/23) of the adverse outcomes observed for this later period involve direct measures of morbidity.[4]

While some adverse outcomes were observed for many conditions in the pilot study, there are a number of conditions for which none was observed (see Tables III.5 and 111.6). Moreover, concentrations of adverse outcomes occur for the Toileting and Pain Management guidelines. These concentrations are associated with the measures of impaction and pain and disappear if these problematic measures are excluded.

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[3]These include observations for which information on the adequacy of care was missing.

[4]As explained in Chapter II, we were interested only in adverse outcomes which might be associated with inadequate care in the two weeks following discharge, and thus only morbidities which might not appear immediately (decubitus and contractures) were measured for the later period. In addition, depression was measured only at six weeks because we wished to exclude short-lived depression.

TABLE C.4

TYPES OF ADVERSE OUTCOMES THAT OCCURRED IN
PILOT STUDY DATA
(Number)

Adverse Outcomes	Problematic Measures Included		Problematic Measures Excluded	
	Weeks One through Two	Weeks Three through six	Weeks One through TWO	Weeks Three through six
Unexpected Use of Health Servicer				
Hospital readmission	2	6	2	6
Emergency room	4	1	4	1
Physician's office or clinic	3	9	3	9
Nursing home admission	0	0	0	0
Subtotal Service Use	9	16	9	16
Morbidity				
Impaction	18	a	1	a
Pain which interferes with daily activities	16	a	0	a
Fall	15	a	3	a
Pain which interferes with sleep	14	a	0	a
Skin breakdown	9	a	9	a
Urinary incontinence	7	a	7	a
Urinary tract infection	5	a	0	a
Hypoglycemia	5	a	5	a
Hyperglycemia	4	a	4	a
Decubitus	2	7	2	7
Contractures	1	0	1	0
Other	0	0	0	0
Subtotal Morbidity	96	7	32	7
Total	105	28	41	23

[a]Not measured during weeks three to six.

c.14

Figure C.3 presents highlights of the results on adverse outcomes. Figure **C.3a** is based on information which indicates that from13 to 23 percent of Medicare patients experienced adverse outcomes, depending on which treatment of missing data and of the problematic measures is used; the figure presents the midpoint of this range, 18 percent. Figure C. 3b is based on information from Table C.4 which indicates that from 61 to 80 percent of the observed outcomes involve morbidity, depending on the treatment of the problematic measures; the figure presents the midpoint, 70 percent. A similar figure for all applicable guidelines (as opposed to patients), with problematic measures excluded, is presented in the Executive Summary.

3. Preliminary Estimates **by** Risk **Group**

Table C.5 presents preliminary estimates of the percentage of the hospitalized Medicare population discharged to the community at various levels of risk of experiencing care that did not meet the Basic Guidelines and of suffering adverse outcomes. The estimates in the table are based on the screening sample, which consists of the 846 patients for whom the screening interviews were **completed.**[5] As the table indicates, about 21 percent of the patients who were screened were identified as at high risk of care that did not meet the guidelines **and** of suffering adverse outcomes, based on the revised risk classification procedures. About 19 percent were classified as at high risk under the original procedures but **not** under the revised procedures. These patients are the group identified as at "moderate risk" in Table C.5. About 55 percent of the patients were classified as at low risk.
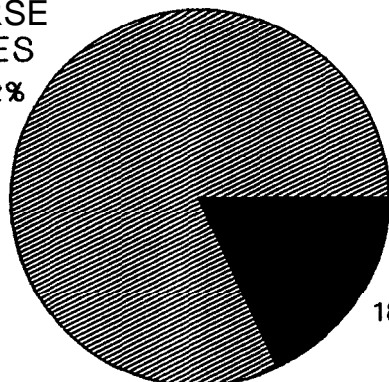

'These 846 completed interviews represent 88.3 percent of the patients for whom the screening **interviews were** attempted. Thus, bias due to non-response is not a serious concern.

FIGURE C.3
ADVERSE OUTCOMES UNDER GUIDELINES

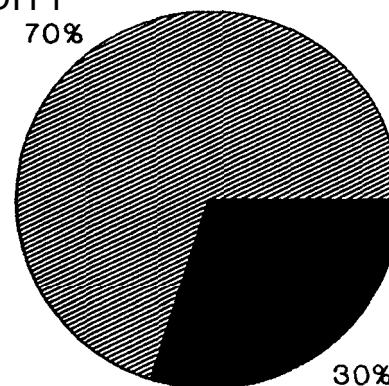3a)

3b)

NO ADVERSE
OUTCOMES
82%

ADVERSE
OUTCOMES
18%

MORBIDITY
70%

UNEXPECTED
HEALTH
SERVICE USE

30%

PATIENTS SUFFERING
ADVERSE OUTCOMES

ALL ADVERSE OUTCOMES
SUFFERED

NOTE: When the estimates involve a range, the midpoint of
that range is used. The treatment of missing data
and of problematic measures was varied in developing
the range.

TABLE C.5

PRELIMINARY ESTIMATES OF THE PERCENTAGE OF HOSPITALIZED
MEDICARE POPULATION AT VARIOUS RISK LEVELS

Risk of Inadequate Care and Adverse Outcomes	Mean	Standard Error	95% Confidence Interval
At High Risk	20.57	1.39	17.89 - 23.29
At Moderate Risk[a]	18.79	1.34	16.16 - 21.42
At Low Risk	54.61	1.71	51.25 - 57.97
Care Not Needed[b]	6.03	0.82	4.43 - 7.63

[a]These patients were those identified as at high risk under the original screening criteria, but **not** under the revised criteria.

[b]These cases were screened out as not requiring care: however, some patients in this group needed care according to the guidelines, and some experienced care that did not meet the Basic Guidelines. Consequently, we treated this group as at risk in estimating the percentage of the population who experienced inadequate care and adverse outcomes.

Finally, about 6 percent **were** classified as not needing care according to the screen. Despite the fact that the screen identified these patients as not needing care, some of the patients in this group did need care according to the Basic Guidelines, and some of them experienced care that did not meet these guidelines. Thus, the group of patients identified as not needing care according to the screen is actually at risk. Accordingly, we included a separate risk level for them.

Table C.6 presents preliminary estimates of the percentage of the hospitalized Medicare population discharged to the community at various risk levels who experienced care that did not meet the Basic Guidelines and who suffered adverse outcomes during weeks one through six. The table provides a range of estimates according to scenarios in which: (1) missing data were excluded and included under the assumption that care met the guidelines and that no adverse outcomes were suffered in cases with missing data; and (2) the problematic measures of outcomes were retained and deleted. The likelihood of experiencing care that did not meet the guidelines varies to a moderate extent across the low- to high-risk groups; however, the likelihood of experiencing care that did not meet the guidelines is substantially lower for the group identified by the screen as not needing care. The likelihood of adverse outcomes is substantially higher in the high-risk than in the other risk groups. No adverse outcomes were observed for the no-care group.

4. <u>Summary</u>

These preliminary estimates **suggest** that access to adequate post-hospital care is a relatively serious problem for Medicare patients discharged to the **community**. It appears that, as measured by the guidelines, about 20 to 25 percent of the post-hospital care needs of Medicare patients discharged to the

TABLE C.6

PRELIMINARY ESTINATES OF THE PERCENTAGE OF THE HOSPITALIZEO MEDICARE POPULATION AT VARIOUS RISK LEVELS
WHO EXPERIENCED CARE THAT DID NOT HEET THE GUIDELINES AND WHO SUFFERED ADVERSE OUTCOMES

Measure	High Risk		Moderate Risk		Low Risk		No Care	
	Mean	Standard Error	Mean	Standard Error	Mean	Standard Error	Mean	Standard Error
Experienced Care That Did Not Neet the Guidelines								
Cases with missing data excluded	69.16	4.48	67.27	6.39	50.00	7.14	20.00	10.69
Cases with missing data included[a]	52.86	4.23	52.86	6.01	39.68	6.21	11.54	6.39
Suffered Adverse Outcomes								
Cases with missing data excluded and problematic measures retained[a]	49.49	5.05	22.45	6.02	16.00	5.24	0.00	b
Cases with missing data included and problematic measures deleted[a]	29.28	3.86	10.00	3.61	9.52	3.73	0.00	b
Experienced Care That Did Not Neet the Guidelines and Suffered Adverse Outcomes								
Cases with missing data excluded and problematic measures retained	34.15	5.27	18.18	5.88	10.87	4.64	0.00	b
Cases with missing data included and problematic measures deleted[a]	17.86	3.25	7.14	3.10	6.35	3.10	0.00	b

NOTE: These estimates are based on the pilot study sample of nine hospitals in two states. Therefore, it is inappropriate to view these results as other than preliminary estimates for the national Medicare population.

"Cases with missing data were included under the assumption that care met the guidelines and no adverse outcomes were suffered.

[b]We have not calculated a standard error because it was not technically possible to calculate it for a mean of zero. However, the true percentage of cases with care that did not meet the guidelines and adverse outcomes may be a small positive percentage rather than zero. For example, assume that the true percentage is 2.0 percent: with the sample of 26 cases in the no-care risk group, a 95 percent confidence interval includes 0.

community are not currently being met, and that most of these needs involve skilled care. This need for additional post-hospital care appears to be fairly widespread: slightly less than half of the Medicare patients discharged to the community appear to need some additional care. However, most of the patients who need additional care do not appear to suffer adverse **outcomes** due to an unmet need for care. Adverse outcomes (which may be, but are not necessarily, linked with adequate care) appear to be suffered by about 15 to 20 percent of Medicare patients discharged to the community. Most of the outcomes observed in the pilot study are morbidities that are not serious enough to require a physician or emergency room visit or readmission to the hospital.